

## (DE) EU-Konformitätserklärung

(EN) EU Declaration of conformity | (FR) Déclaration de conformité UE | (IT) Dichiarazione di conformità UE | (ES) Declaración UE de conformidad | (PT) Declaração de conformidade da UE | (NL) EU-conformiteitsverklaring | (EL) Δήλωση συμμόρφωσης ΕΕ | (DA) EU overensstemmelseserklæring | (SV) EU-försäkran om överensstämmelse | (FI) EU-vaatimustenmukaisuusvakuutus | (HU) EU megfelelőségi nyilatkozat | (BG) ЕС Декларация за съответствие | (RO) Declarația de conformitate UE | (CS) EU Prohlášení o shodě | (PL) Deklaracja zgodności UE | (SK) EÚ Vyhlásenie o zhode | (SL) Izjava EU o skladnosti | (HR) Izjava EU o skladnosti | (LV) ES atbilstības deklarācija | (LT) ES atitikties deklaracija | (ET) ELi vastavusdeklaratsioon | (TR) AB Uygunluk Bildirgesi



### Wir (Name & Adresse der Firma)

We (Name and address of manufacturer) | Nous (Nom et adresse du fabricant) | Noi (Nome e indirizzo del fabbricante) | Nosotros (Nombre y dirección del fabricante) | Nós (Nome e endereço do fabricante) | Wij (Naam en adres van de fabrikant) | Εμείς (Όνομα και διεύθυνση του κατασκευαστή) | Vi (Fabrikantens navn og adresse) | Vi (Navn og adresse til produsent) | Me (Valmistajan nimi ja osoite) | Mi (A gyártó neve és címe) | Мне (Име и адрес на производителя) | Noi (Numele și adresa producătorului) | My (Jméno a adresa výrobce) | My (Nazwa i adres producenta) | My (Meno a adresa výrobcu) | Mi (Ime in naslov proizvajalca) | Mi (Naziv i adresa proizvođača) | Mēs (Ražotāja nosaukums un adrese) | Mes (Gamintojo pavadinimas ir adresas) | Me (Tootja nimi ja aadress) | Biz (Üreticinin adı ve adresi)

**TRI® Dental Implants Int. AG**  
**Bösch 80A**  
**CH-6331 Hünenberg**  
**Switzerland**

**SRN: CH-MF-000034885**  
**CHRN: CHRN-MF-20000977**

### erklären in alleiniger Verantwortung, dass das Medizinprodukt

declare under our sole responsibility that the medical devices | déclarons sous notre seule responsabilité que les dispositifs médicaux | dichiariamo sotto la nostra esclusiva responsabilità che i dispositivi medici | declaramos bajo nuestra exclusiva responsabilidad que los productos sanitarios | declarar sob a nossa exclusiva responsabilidade que os dispositivos médicos | verklaren onder onze uitsluitende verantwoordelijkheid dat de medische hulpmiddelen | δηλώνουμε με αποκλειστική μας ευθύνη ότι τα ιατροτεχνολογικά προϊόντα | erklærer på vores eget ansvar, at det medicinske udstyr | på vårt eget ansvar förklara att de medicintekniska produkterna | ilmoitamme yksinomaaisella vastuullamme, että lääkinälliset laitteet ovat | kijelentjük, hogy kizárólagos felelősségünkre az orvostechnikai eszközöket | декларираме на своя отговорност, че медицинските изделия | deklarām pe propria răspundere că dispozitivele medicale | proklašujeme na vlastni odgovornost, že zdravotnícké prostriedky | oświadczamy na naszą wyłączną odpowiedzialność, że wyroby medyczne | vyhlasujeme na vlastnú zodpovednosť, že zdravotnícke pomôcky | na lastno odgovornost izjavljamo, da so medicinski pripomočki | proglašite pod našom jedinom odgovornošću da medicinski proizvodi | paziņojam uz savu atbildību, ka medicīniskās ierīces | išimtinai savo atsakomybe pareiškiame, kad medicinos prietaisai | deklareerida meie ainuvastutusel, et meditsiiniseadmed | tibbi cihazların tamamen bizim sorumluluğumuz altında

### Name

Name | Nom | Nome | Nombre | Nome | Naam | Όνομα | Navn | Namn | Nimi | Név | Име | Nume | Jméno | Nazwa | Meno | Ime | Ime | Vårds | Vardas, pavadinimas | Nimi | Ad

**TRI® Dental Implants Int. AG**

### Artikel & bestimmungsgemäße Verwendung

Article and intended use | Article et usage prévu | Articolo e uso previsto | Artículo y uso previsto | Artigo e utilização prevista | Artikel en beoogd gebruik | Άρθρο και προβλεπόμενη χρήση | Artikel og anvendelsesformål | Artikel och avsedd användning | Artikkel ja käyttötarkoitus | Cikk és rendeltetés szerinti használat | изделие и предназначение | Articolul și utilizarea prevăzută | Článek a zamýšlené použití | Artykul i przeznaczenie | Výrobok a zamýšľané použitie | Člen in predvidena uporaba | Članak i namjena | Izstrādājums un paredzētais lietojums | Straipsnis ir paskirtis | Artikkel ja Sihtotstarve | Ürün ve kullanım amacı

### Siehe Anhang 1

See annex 1 | Voir l'annexe 1 | Cfr. allegato 1 | Ver anexo 1 | Ver anexo 1 | Zie bijlage 1 | Βλέπε παράρτημα 1 | Se bilag 1 | Se bilaga 1 | Katso liite 1 | Lásd az 1. mellékletet | Вк. приложение 1 | Vezi anexa 1 | Viz příloha 1 | Patrz załącznik 1 | Pozri prílohu 1 | Glej Prilogo 1 | Vidi prilog 1 | Skatīt 1. pielikumu | Žr. 1 priedas | Vt 1. lisa | Bkz. ek 1

### alle Anforderungen der Verordnung (EU) 2017/745 erfüllen

comply with all requirements of regulation (EU) 2017/745 | se conformer à toutes les exigences du règlement (UE) 2017/745 | rispettare tutti i requisiti del regolamento (UE) 2017/745 | cumplir todos los requisitos del Reglamento (UE) 2017/745 | cumprir todos os requisitos de regulamentação (UE) 2017/745 | voldoen aan alle vereisten van Verordening (EU) 2017/745 | συμμορφώνονται με όλες τις απαιτήσεις του κανονισμού (ΕΕ) 2017/745 | opfylde alle krav i forordning (EU) 2017/745 | uppfylla alla krav i förordning (EU) 2017/745 | noudattettava kaikkia asetusten (EU) 2017/745 vaatimuksia | megfelel az (EU) 2017/745 rendelet valamennyi követelményének | отговарят на всички изисквания на Регламент (ЕС) 2017/745 | są respectate toate cerințele Regulamentului (UE) 2017/745 | splňovat všechny požadavky nařízení (EU) 2017/745 | spełniać wszystkie wymagania rozporządzenia (UE) 2017/745 | splniat všetky požiadavky nariadenia (EÚ) 2017/745 | izpolnjevati vse zahteve uredbe (EU) 2017/745 | u skladu sa svim zahtjevima uredbe (EU) 2017/745 | atbilst visām Regulas (ES) 2017/745 prasībām, | laikytis visų Reglamento (ES) 2017/745 reikalavimų | vastavad kõigile määruse (EL) 2017/745 nõuetele | 2017/745 sayılı yönetmeliğin tüm gerekliliklerine uymak

### EU Bevollmächtigter

EU Authorized Representative | Représentant autorisé de l'UE | Rappresentante autorizzato UE | Representante autorizado de la UE | Representante autorizado da UE | Gemachtigde vertegenwoordiger van de EU | Εξουσιοδοτημένος Αντιπρόσωπος της ΕΕ | EU-representant | EU:s representant | EU:n valtuutettu edustaja | Az EU meghatalmazott képviselője | Упълномощен представител на ЕС | Reprezentantul autorizat al UE | Zplnomocnený zástupce EU | Upraważniony przedstawiciel UE | Splnomocnený zástupca EÚ | Pooblaščení predstavnik EU | Ovlašteni predstavnik EU-a | ES pilnvarotais pārstāvis | ES įgaliotasis atstovas | ELi volitatud esindaja | AB Yetkilili Temsilcisi

**TRI® Dental Implants Direct**  
**GmbH**  
**Merzhauser Strasse 183**  
**79110 Freiburg**  
**Germany**

**SRN: DE-AR-000005806**

# (DE) EU-Konformitätserklärung

(EN) EU Declaration of conformity | (FR) Déclaration de conformité UE | (IT) Dichiarazione di conformità UE | (ES) Declaración UE de conformidad | (PT) Declaração de conformidade da UE | (NL) EU-conformiteitsverklaring | (EL) Δήλωση συμμόρφωσης ΕΕ | (DA) EU overensstemmelseserklæring | (SV) EU-försäkran om överensstämmelse | (FI) EU-vaatimustenmukaisuusvakuutus | (HU) EU megfelelőségi nyilatkozat | (BG) ЕС Декларация за съответствие | (RO) Declarația de conformitate UE | (CS) EU Prohlášení o shodě | (PL) Deklaracja zgodności UE | (SK) EÚ Vyhlasenie o zhode | (SL) Izjava EU o skladnosti | (HR) Izjava EU o sukladnosti | (LV) ES atbilstības deklarācija | (LT) ES atitikties deklaracija | (ET) ELi vastavusdeklaratsioon | (TR) AB Uygunluk Bildirgesi



## Klassifizierung nach Anhang VIII (EU) 2017/745

Classification according to Annex VIII (EU) 2017/745 | Classification selon l'annexe VIII (UE) 2017/745 | Classificazione secondo l'allegato VIII (UE) 2017/745 | Clasificación según el anexo VIII (UE) 2017/745 | Classificação de acordo com o anexo VIII (UE) 2017/745 | Indeling volgens bijlage VIII (EU) 2017/745 | Ταξινόμηση σύμφωνα με το παράρτημα VIII (ΕΕ) 2017/745 | Klassificering i henhold til bilag VIII (EU) 2017/745 | Klassificering enligt bilaga VIII (EU) 2017/745 | Luokitus liitteeseen VIII (EU) 2017/745 mukaisesti | Besorolás a VIII. melléklet (EU) 2017/745 szerint | Класификация съгласно приложението VIII (ЕС) 2017/745 | Clasificarea în conformitate cu anexa VIII (UE) 2017/745 | Zařazení podle přílohy VIII (EU) 2017/745 | Klasifikacja zgodnie z załącznikiem VIII (UE) 2017/745 | Klasifikācija podľa pielikuma VIII (EŪ) 2017/745 | Razvrstitev v skladu s Prilogo VIII (EU) 2017/745 | Razvrstavanje prema Prilogu VIII. (EU) 2017/745 | Klasifikācija saskaņā ar VIII pielikumu (ES) 2017/745 | Klasifikavimas pagal VIII priedą (ES) 2017/745 | Klassifikatsioon vastavalt VIII lisale (EL) 2017/745 | Ek VIII (AB) 2017/745'e göre sınıflandırma

## Klasse

Class  
Classe  
Classe  
Classe  
Classe  
Classe  
Klas  
Κλάση  
Klasse  
Klass  
Luokka  
Osztály  
Knaca  
Clasă  
Třída  
Klasa  
Trieda  
Razred  
Klasa  
Klase  
Klasé  
Klass  
Sinif

## Regel

Rule  
Règle  
Regola  
Regla  
Regra  
Regel  
Κανόνας  
Regel  
Regel  
Sääntö  
Szabály  
Правило  
Regulă  
Pravidlo  
Regula  
Pravidlo  
Pravilo  
Pravilo  
Noteikums  
Taisyklė  
Reegel  
Kural

5 (first  
ident)

## Konformitätsbewertungsverfahren nach (EU) 2017/745

Conformity assessment procedure according EU 2017/745 | Procédure d'évaluation de la conformité selon l'UE 2017/745 | Procedura di valutazione della conformità secondo l'UE 2017/745 | Procedimiento de evaluación de la conformidad según la UE 2017/745 | Procedimento de avaliação da conformidade de acordo com a UE 2017/745 | Conformiteitsbeoordelingsprocedure volgens EU 2017/745 | Διαδικασία αξιολόγησης της συμμόρφωσης σύμφωνα με την ΕΕ 2017/745 | Procedure for overensstemmelsesvurdering i henhold til EU 2017/745 | Förfarande för bedömning av överensstämmelse enligt EU 2017/745 | EU:n 2017/745 mukainen vaatimustenmukaisuuden arviointimenettely | Az EU 2017/745 szerinti megfelelőségértékelési eljárás | Процедура за оценяване на съответствието съгласно ЕС 2017/745 | Procedura de evaluare a conformității în conformitate cu UE 2017/745 | Postup posuzování shody podle EU 2017/745 | Procedura oceny zgodności według UE 2017/745 | Postup posudzowania zhody podľa EÚ 2017/745 | Postopek ugotavljanja skladnosti v skladu z EU 2017/745 | Postupak ocjenjivanja sukladnosti prema EU 2017/745 | Atbilstības novērtēšanas procedūra saskaņā ar ES 2017/745 | Atitikties vertinimo procedūra pagal ES 2017/745 | Vastavushindamismenetlus vastavalt EL 2017/745 | AB 2017/745'e göre uygunluk değerlendirme prosedürü

## Anhang

Annex  
Annexe  
Allegato  
Anexo  
Anexo  
Bijlage  
Παράρτημα  
Bilag  
Bilaga  
Liite  
Melléklet  
Приложение  
Anexa  
Příloha  
Załącznik  
Priloha  
Priloga  
Prilog  
Pielikums  
Priedas  
Lisa  
Ek

IX

## Angewandte harmonisierte Normen

applied harmonised standards | normes harmonisées appliquées | norme armonizzate applicate | normas armonizadas aplicadas | padrões harmonizados aplicados | toegepaste geharmoniseerde normen | εφαρμοσμένα εναρμονισμένα πρότυπα | anvendte harmoniserede standarder | tillämpade harmoniserade standarder | sovelletuista yhdenmukaistetuista standardeista | harmonizált szabványok alkalmazása | прилагани хармонизирани стандарти | standarde armonizate aplicate | uplatňované harmonizované normy | stosowane normy zharmonizowane | uplatňované harmonizované normy | uporabljenih usklajenih standardov | primijenjene usklađene norme | piemērotie saskaņotie standarti | taikomi darnieji standartai | kohaldatud harmoneeritud standardid | uygulanan uyumlaştırılmış standartlar

## Siehe Dokument

See document | Voir le document | Cfr. documento | Ver document | Ver documento | Zie document | Βλέπε έγγραφο | Se dokument | Se dokumentet | Katso asiakirja | Lásd a dokumentumot | Вж. документа | Vezi documentul | Viz dokument | Patrz dokument | Pozri dokument | Glej dokument | Vidi document | Skatit dokumentu | Žr. dokumentą | Vt document | Belgeye bakın

REC\_Regulatory  
List\_TRI Dental  
Implant  
System\_07

Hünenberg, 20 / 06 / 2023

СТО

## Ort, Datum

Place, Date | L'endroit, Date | Luogo, Data | Place, Fecha | Lugar, Data | Plaats, Datum | Τόπος, Ημερομηνία | Sted, Dato | Plats, Datum | Paikka, Päivämäärä | Hely, Dátum | Место, Дата | Loc, Dată | Misto, Rande | Miejsce, Data | Miesto, Datum | Mesto, Datelj | Mjesto, Datum | Vieta, Datums | Vieta, Data | Koht, Kuupäev | Yer, Tarih

## Name & Funktion

Name and function | Nom et fonction | Nome e funzione | Nombre y función | Nome e função | Naam en functie | Όνομα και λειτουργία | Navn og funktion | Namn och funktion | Nimi ja funktio | Név és funkció | Име и функция | Nume și funcție | Název a funkce | Nazwa i funkcja | Názov a funkcia | Ime in funkcija | Naziv i funkcija | Nosaukums un amats | Pavadinimas ir funkcija | Nimi ja funktsioon | Ad ve islev

## (DE) EU-Konformitätserklärung

(EN) EU Declaration of conformity | (FR) Déclaration de conformité UE | (IT) Dichiarazione di conformità UE | (ES) Declaración UE de conformidad | (PT) Declaração de conformidade da UE | (NL) EU-conformiteitsverklaring | (EL) Δήλωση συμμόρφωσης ΕΕ | (DA) EU overensstemmelseserklæring | (SV) EU-försäkran om överensstämmelse | (FI) EU-vaatimustenmukaisuusvakuutus | (HU) EU megfelelőségi nyilatkozat | (BG) ЕС Декларация за съответствие | (RO) Declarația de conformitate UE | (CS) EU Prohlášení o shodě | (PL) Deklaracja zgodności UE | (SK) EÚ Vyhlásenie o zhode | (SL) Izjava EU o skladnosti | (HR) Izjava EU o skladnosti | (LV) ES atbilstības deklarācija | (LT) ES atitikties deklaracija | (ET) ELi vastavusdeklaratsioon | (TR) AB Uygunluk Bildirgesi



### Anhang 1

Annex 1 | Annexe 1 | Allegato 1 | Anexo 1 | Anexo 1 | Bijlage 1 | Παράρτημα 1 | Bilag 1 | Bilaga 1 | Liite 1 | 1. Melléklet | Приложение 1 | Anexa 1 | Píloha 1 | Załącznik 1 | Príloha 1 | Priloga 1 | Prilog 1 | 1. Pielikums | 1. Priedas | 1. Lisa | Ek 1

| Bestimmungsgemäße Verwendung   | DE | TRI® Dental Implant-Instrumente dienen zur Planung und Platzierung von Implantaten des TRI® Dental Implant Systems. Die jeweiligen Kassetten dienen zur Aufbewahrung und Sterilisation der Instrumente.                  |
|--------------------------------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended use                   | IE | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Usage prévu                    | FR | Les instruments TRI® sont destinés à la planification et à la mise en place d'implants du TRI® Dental Implant System. Les cassettes sont utilisées pour ranger et stériliser les instruments.                            |
| Uso previsto                   | IT | Los instrumentos TRI® Dental Implant están diseñados para ser usados en la planificación y colocación de implantes del TRI® Dental Implant System. Las cajas se utilizan para almacenar y esterilizar los instrumentos.  |
| Uso previsto                   | ES | Los taladros quirúrgicos son manufacturados de acero inoxidable 1.4614 incluyendo una capa de DLC. Los drivers de implantes se manufacturan de acero inoxidable 1.034.                                                   |
| Utilização Prevista            | PT | Os TRI® Instrumentos de Implantes Dental são destinados a serem utilizados para planejar e colocar os implantes do TRI® Sistema de Implante Dental. As gavetas são utilizadas para armazenar e esterilizar instrumentos. |
| Beoogd gebruik                 | NL | De chirurgische boren zijn gemaakt van roestvrij staal 1.4614 inclusief DLC-coating. De implantaat drivers zijn gemaakt van roestvrij staal 1.4034                                                                       |
| Προβλεπόμενη χρήση             | GR | Οι χειρουργικές φρέζες είναι κατασκευασμένες από ανοξείδωτο ατσάλι 1.4614 με επίστρωση DLC. Οι οδηγόι εμφυτεύματος είναι κατασκευασμένοι από ανοξείδωτο ατσάλι 1.4034.                                                   |
| Anvendelsesformål              | DK | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Avsedd användning              | SE | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Käyttötarkoitus                | FI | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Rendeltetés szerinti használat | HU | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Предназначение                 | BG | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Utilizare prevăzută            | RO | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Zamýšlené použití              | CZ | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Przeznaczenie                  | PL | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Zamýšľané použitie             | SK | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Predvidena uporaba             | SI | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Namjena                        | HR | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Paredzētais lietojums          | LV | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Paskirtis                      | LT | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Sihtotstarve                   | EE | The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.                  |
| Kullanım Amacı                 | TR | TRI® aletleri, implantların TRI Dental Implant Sistemine göre planlanması ve yerleştirilmesi amacıyla kullanılmak üzere tasarlanmıştır. Kasetler, aletleri saklamak ve sterilize etmek için kullanılır                   |

# (DE) EU-Konformitätserklärung

(EN) EU Declaration of conformity | (FR) Déclaration de conformité UE | (IT) Dichiarazione di conformità UE |  
(ES) Declaración UE de conformidad | (PT) Declaração de conformidade da UE | (NL) EU-conformiteitsverklaring |  
(EL) Δήλωση συμμόρφωσης ΕΕ | (DA) EU overensstemmelseserklæring | (SV) EU-försäkran om överensstämmelse |  
(FI) EU-vaatimustenmukaisuusvakuutus | (HU) EU megfelelőségi nyilatkozat | (BG) ЕС Декларация за съответствие |  
(RO) Declarația de conformitate UE | (CS) EU Prohlášení o shodě | (PL) Deklaracja zgodności UE | (SK) EÚ Vyhlásenie o zhode |  
(SL) Izjava EU o skladnosti | (HR) Izjava EU o skladnosti | (LV) ES atbilstības deklarācija | (LT) ES atitikties deklaracija |  
(ET) ELi vastavusdeklaratsioon | (TR) AB Uygunluk Bildirgesi



| Artikelnummer                                                                                                                                                                                                                                                                                                                                                                                                                 | Basis UDI-DI                                                                                                                                                                                                                                                                                                                                           | Beschreibung                                                                                                                                                                                                                                                                | GMDN                                                                                                                                                                 | Klasse                                                                                                                                                                                                                          | Regel                                                                                                                                                                                                                                           | Hinzugefügt am                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Article number<br>Numéro d'article<br>Numero<br>dell'articolo<br>Número de<br>artículo<br>Número do artigo<br>Artikelnummer<br>Αριθμός άρθρου<br>Artikkelnummer<br>Artikkelnummer<br>Artikkelin numero<br>Cikkszám<br>Номер на статия<br>Numărul articolului<br>Číslo článku<br>Numer artykułu<br>Číslo článku<br>Številka izdelka<br>Broj članka<br>Raksta numurs<br>Straipsnio numeris<br>Artikli number<br>Makale numarasi | Basic UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Basis UDI-DI<br>Basis UDI-DI<br>Bas UDI-DI<br>Perusta UDI-DI<br>Alap UDI-DI<br>Основа UDI-DI<br>Baza UDI-DI<br>Základ UDI-DI<br>Kod UDI-DI podstawy<br>Základ UDI-DI<br>Osnova UDI-DI<br>Osnova UDI-DI<br>Pamats UDI-DI<br>Pagrindas UDI-DI<br>Alus UDI-DI<br>Temel UDI-DI | Description<br>Description<br>Descrizione<br>Descripción<br>Description<br>Beschrijving<br>Περιγραφή<br>Beskrivelse<br>Beskrivning<br>Kuvaus<br>Leírás<br>Описание<br>Descrerie<br>Popis<br>Opis<br>Popis<br>Opis<br>Opis<br>Apraksts<br>Apibūdinimas<br>Kirjeldus<br>Tarif | GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN | Class<br>Classe<br>Classe<br>Classe<br>Classe<br>Klas<br>Klasse<br>Klasse<br>Klasse<br>Klass<br>Luokka<br>Osztály<br>Klasa<br>Clasă<br>Třída<br>Klasa<br>Klasa<br>Trieda<br>Razred<br>Klasa<br>Klase<br>Klasé<br>Klass<br>Sinif | Rule<br>Règle<br>Regola<br>Regla<br>Regla<br>Regel<br>Regel<br>Regel<br>Regel<br>Regel<br>Sääntö<br>Szabály<br>Правило<br>Regulă<br>Pravidlo<br>Regula<br>Pravidlo<br>Pravilo<br>Pravilo<br>Pravilo<br>Noteikums<br>Taisyklė<br>Reegel<br>Kural | Date added<br>Date d'ajout<br>Aggiunto in data<br>Fecha de adición<br>Date added<br>Datum toegevoegd<br>Προσθήκη ημερομηνίας<br>Dato tilføjet<br>Datum tillagt<br>Sääntö<br>Hozzáadás dátuma<br>Дата на добавяне<br>Data adăugării<br>Datum přidání<br>Data dodania<br>Dodan datum<br>Datum dodavanja<br>Pievienošanas datums<br>Pridēta data<br>Lisamise kuupäev<br>Eklenme tarihi |
| M-IMPR-L-37-P37                                                                                                                                                                                                                                                                                                                                                                                                               | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer<br>Component-Long-Ø 3.7mm-P37                                                                                                                                                                                                                       | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| M-IMPR-L-50-P45                                                                                                                                                                                                                                                                                                                                                                                                               | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer<br>Component-Long-Ø 5mm-P45                                                                                                                                                                                                                         | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TV05-35                                                                                                                                                                                                                                                                                                                                                                                                                       | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | TV Direct Transfer Component incl.<br>DTRS - Ø 3.5 mm                                                                                                                                                                                                                       | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TV05-50                                                                                                                                                                                                                                                                                                                                                                                                                       | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | TV Direct Transfer Component incl.<br>DTRS - Ø 5 mm                                                                                                                                                                                                                         | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| DTRS-TV05                                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Direct Transfer Retaining Screw for<br>TV05                                                                                                                                                                                                                                 | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| M-RS-IMPR-L                                                                                                                                                                                                                                                                                                                                                                                                                   | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer Retaining<br>Screw - Long                                                                                                                                                                                                                           | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TN05-35                                                                                                                                                                                                                                                                                                                                                                                                                       | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | TN Direct Transfer Component incl.<br>DTRS - Ø 3.5mm                                                                                                                                                                                                                        | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TN10-35-ITC                                                                                                                                                                                                                                                                                                                                                                                                                   | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | TN 2in1 Impression Abutment - Ø<br>3.5 mm                                                                                                                                                                                                                                   | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| DTRS-TN05                                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Direct Transfer Retaining Screw for<br>TN05-35                                                                                                                                                                                                                              | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| M-IMPR-S-37-P37                                                                                                                                                                                                                                                                                                                                                                                                               | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer<br>Component-Short-Ø3.7mm-P37                                                                                                                                                                                                                       | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| M-IMPR-S-50-P45                                                                                                                                                                                                                                                                                                                                                                                                               | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer<br>Component-Short-Ø 5mm-P45                                                                                                                                                                                                                        | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TO05-51                                                                                                                                                                                                                                                                                                                                                                                                                       | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | TO Direct Transfer Component incl.<br>DTRS - Ø 5.1 mm                                                                                                                                                                                                                       | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| DTRS-TO05                                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Direct Transfer Reatining Screw for<br>TO05-51                                                                                                                                                                                                                              | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| M-RS-IMPR-S                                                                                                                                                                                                                                                                                                                                                                                                                   | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                        | Matrix®-Direct Transfer Retaining<br>Screw - Short                                                                                                                                                                                                                          | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| PD-L                                                                                                                                                                                                                                                                                                                                                                                                                          | 764014988INAN8                                                                                                                                                                                                                                                                                                                                         | TRI® Prosthetic Driver - Long                                                                                                                                                                                                                                               | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| PD-S                                                                                                                                                                                                                                                                                                                                                                                                                          | 764014988INAN8                                                                                                                                                                                                                                                                                                                                         | TRI® Prosthetic Driver - Short                                                                                                                                                                                                                                              | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TORT                                                                                                                                                                                                                                                                                                                                                                                                                          | 764014988INAN8                                                                                                                                                                                                                                                                                                                                         | Removal Tool for TRI®-Octa<br>Friction Abutments                                                                                                                                                                                                                            | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TRT                                                                                                                                                                                                                                                                                                                                                                                                                           | 764014988INAN8                                                                                                                                                                                                                                                                                                                                         | Removal Tool for TRI®-Vent &<br>Narrow Friction Abut.                                                                                                                                                                                                                       | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |
| TW                                                                                                                                                                                                                                                                                                                                                                                                                            | 764014988INAN8                                                                                                                                                                                                                                                                                                                                         | Torque Wrench - 10-45 Ncm                                                                                                                                                                                                                                                   | 55847                                                                                                                                                                | I                                                                                                                                                                                                                               | 5 (first<br>ident)                                                                                                                                                                                                                              | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                          |

(EN) EU Declaration of conformity | (FR) Déclaration de conformité UE | (IT) Dichiarazione di conformità UE | (ES) Declaración UE de conformidad | (PT) Declaração de conformidade da UE | (NL) EU-conformiteitsverklaring | (EL) Δήλωση συμμόρφωσης ΕΕ | (DA) EU overensstemmelseserklæring | (SV) EU-försäkran om överensstämmelse | (FI) EU-vaatimustenmukaisuusvakuutus | (HU) EU megfelelőzési nyilatkozat | (BG) ЕС Декларация за съответствие | (RO) Declarația de conformitate UE | (CS) EU Prohlášení o shodě | (PL) Deklaracja zgodności UE | (SK) EU Vyhlásenie o zhode | (SL) Izjava EU o skladnosti | (HR) Izjava EU o sukladnosti | (LV) ES atbilstības deklarācija | (LT) ES atitikties deklaracija | (ET) ELi vastavusdeklaratsioon | (TR) AB Uygunluk Bildirgesi

| Artikelnummer                                                                                                                                                                                                                                                                                                                                                                                               | Basis UDI-DI                                                                                                                                                                                                                                                                                                                                                          | Beschreibung                                                                                                                                                                                                                                                                         | GMDN                                                                                                                                                                                         | Klasse                                                                                                                                                                                                                       | Regel                                                                                                                                                                                                                                                         | Hinzugefügt am                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Article number<br>Numéro d'article<br>Numero<br>dell'articolo<br>Número de<br>artículo<br>Número do artigo<br>Artikelnummer<br>Αριθμός άρθρου<br>Artikkelnummer<br>Artikkelin numero<br>Cikkszám<br>Номер на статия<br>Numărul articolului<br>Číslo článku<br>Numer artykułu<br>Číslo článku<br>Številka izdelka<br>Broj članka<br>Raksta numurs<br>Straipsnio numeris<br>Artikli number<br>Makale numarası | Basic UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Base UDI-DI<br>Basis UDI-DI<br>Βάση UDI-DI<br>Βασίς UDI-DI<br>Bas UDI-DI<br>Perusta UDI-DI<br>Alap UDI-DI<br>Основа UDI-DI<br>Baza UDI-DI<br>Základ UDI-DI<br>Kód UDI-DI podstawy<br>Základ UDI-DI<br>Osnova UDI-DI<br>Osnova UDI-DI<br>Pamats UDI-DI<br>Pagrindas UDI-DI<br>Alus UDI-DI<br>Temel UDI-DI | Description<br>Description<br>Descrizione<br>Descripción<br>Description<br>Beschrijving<br>Περιγραφή<br>Beskrivelse<br>Beskrivning<br>Kuvaus<br>Leírás<br>Описание<br>Descriere<br>Popis<br>Opis<br>Popis<br>Opis<br>Opis<br>Opis<br>Apiraksts<br>Apibūdinimas<br>Kirjeldus<br>Tarif | GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN<br>GMDN | Class<br>Classe<br>Classe<br>Clase<br>Classe<br>Klas<br>Κλάση<br>Klasse<br>Klass<br>Luokka<br>Osztály<br>Klaca<br>Clasă<br>Třída<br>Klasa<br>Klass<br>Trieda<br>Razred<br>GMDN<br>Klasa<br>Klasse<br>Klasé<br>Klass<br>Sinif | Rule<br>Règle<br>Regola<br>Regla<br>Regra<br>Regel<br>Κανόνας<br>Προσθήκη ημερομηνίας<br>Dato tilføjet<br>Regel<br>Sääntö<br>Szabály<br>Правило<br>Regulă<br>Pravidlo<br>Regula<br>Pravidlo<br>Pravilo<br>Pravilo<br>Noteikums<br>Taisyklė<br>Reegel<br>Kural | Date added<br>Date d'ajout<br>Aggiunto in data<br>Fecha de adición<br>Date added<br>Datum toegevoegd<br>Προσθήκη ημερομηνίας<br>Dato tilføjet<br>Regel<br>Sääntö<br>Hozzáadás dátuma<br>Дата на добавяне<br>Data adăugării<br>Datum pridáního<br>Data dodania<br>Datum pridania<br>Dodan datum<br>Datum dodavanja<br>Pievienošanas datums<br>Pridėta data<br>Lisamise kuupäev<br>Eklenme tarihi |
| TW-Adapter                                                                                                                                                                                                                                                                                                                                                                                                  | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Torque Wrench Adapter                                                                                                                                                                                                                                                                | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GFP                                                                                                                                                                                                                                                                                                                                                                                                         | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Fixation Pin                                                                                                                                                                                                                                                                  | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GFP-Sleeve                                                                                                                                                                                                                                                                                                                                                                                                  | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Fixation Pin Sleeve                                                                                                                                                                                                                                                           | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GIM-BLM                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Implant Mount-Bone Level<br>matrix®                                                                                                                                                                                                                                           | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GIM-Narrow                                                                                                                                                                                                                                                                                                                                                                                                  | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Implant Mount-Narrow                                                                                                                                                                                                                                                          | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GIM-Octa                                                                                                                                                                                                                                                                                                                                                                                                    | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Implant Mount-Octa                                                                                                                                                                                                                                                            | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GIM-TLM                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Implant Mount-Tissue Level<br>matrix®                                                                                                                                                                                                                                         | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GIM-Vent                                                                                                                                                                                                                                                                                                                                                                                                    | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Implant Mount-Vent                                                                                                                                                                                                                                                            | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| GS                                                                                                                                                                                                                                                                                                                                                                                                          | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Sleeve                                                                                                                                                                                                                                                                        | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| MD-L-TW                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Matrix® Implant Driver - Long - for<br>TW                                                                                                                                                                                                                                            | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| MD-S-TW                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Matrix® Implant Driver - Short - for<br>TW                                                                                                                                                                                                                                           | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| PP-L                                                                                                                                                                                                                                                                                                                                                                                                        | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Parallel Pins - Long                                                                                                                                                                                                                                                                 | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| TPDS                                                                                                                                                                                                                                                                                                                                                                                                        | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | Guided Surgery Sleeve for TPD (3<br>pcs.)                                                                                                                                                                                                                                            | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| VD-L-TW                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | TRI®-Vent Implant Driver - Long -<br>for TW                                                                                                                                                                                                                                          | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| VD-S-TW                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988INAN8                                                                                                                                                                                                                                                                                                                                                        | TRI®-Vent Implant Driver - Short -<br>for TW                                                                                                                                                                                                                                         | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| DTC-SRA                                                                                                                                                                                                                                                                                                                                                                                                     | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                                       | Direct Transfer Component for<br>Screw-Retained Abut                                                                                                                                                                                                                                 | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |
| DTRS-SRA                                                                                                                                                                                                                                                                                                                                                                                                    | 764014988IMPRKC                                                                                                                                                                                                                                                                                                                                                       | Direct Transfer Retaining Screw                                                                                                                                                                                                                                                      | 55847                                                                                                                                                                                        | I                                                                                                                                                                                                                            | 5 (first<br>ident)                                                                                                                                                                                                                                            | 20/06/2023                                                                                                                                                                                                                                                                                                                                                                                      |

|                         |                                          |
|-------------------------|------------------------------------------|
| Title                   | EC Declaration of conformity class 1_01  |
| File name               | EC Declaration of...y class 1_01.docx    |
| Document ID             | 06a79c26710c7744485ce101a9a74e3b1d70128f |
| Audit trail date format | DD / MM / YYYY                           |
| Status                  | ● Signed                                 |

## Document History



SENT

**20 / 06 / 2023**

15:29:13 UTC+2

Sent for signature to Sandro Venanzoni (sv@tri.swiss) from  
veronique.arnegger@tri-implants.swiss  
IP: 87.123.206.125



VIEWED

**20 / 06 / 2023**

15:58:12 UTC+2

Viewed by Sandro Venanzoni (sv@tri.swiss)  
IP: 46.14.72.90



SIGNED

**20 / 06 / 2023**

15:58:27 UTC+2

Signed by Sandro Venanzoni (sv@tri.swiss)  
IP: 46.14.72.90



COMPLETED

**20 / 06 / 2023**

15:58:27 UTC+2

The document has been completed.

**EC Declaration of Conformity**  
EC Directive 93/42/EEC Annex II, excluded point 4  
**Full Quality Assurance System**  
**Medical Devices**

Registration No.: 535987 MR2  
Certification No.: 170739372 (issued 2019-12-01)

Manufacturer: **TRI® Dental Implants Int. AG**  
**Bösch 80A**  
**CH-6331 Hünenberg**  
**Switzerland**

Scope: TRI® Dental Implant System:  
• TRI® Dental Implants  
• TRI® Dental Abutment

This declaration of conformity is valid until 2024-05-26 and remains valid subject to satisfactory surveillance audits.

We, the company TRI® Dental Implants Int. AG, hereby declare, that we are exclusively responsible for the declaration of conformity and that the distributed CE marked products, specified in the annex 1 product list, are in compliance with the Essential Requirements as defined by the provisions of Council Directive 93/42/EEC Annex I.

The medical devices listed above have been classified according to the classification rules according to Council Directive 93/42/EEC Annex IX and have met all the applicable conformity assessment elements. The conformity assessment procedure has been applied according to Council Directive 93/42/EEC Annex II, excluded point 4.

Notified Body:  
DQS 0297  
DQS Medizinprodukte GmbH  
August-Schanz-Str. 21  
60433 Frankfurt am Main,  
Germany

As part of the conformity the norms of the CE registration are fulfilled:

REC\_Regulatory List\_TRI Dental Implant System\_08.

Sandro Venanzoni  
Hünenberg, 2023-07-21



Sandro Venanzoni - CTO



## EC Declaration of Conformity

### Annex 1: Product List

| Article No.                               | Name                                                    | Class According to Annex IX of directive 93/42/EEC |
|-------------------------------------------|---------------------------------------------------------|----------------------------------------------------|
| <b>TRI® Dental Implants - TRI®-Vent</b>   |                                                         |                                                    |
| TV37M08                                   | TRI® Vent Implant Ø 3.75mm - L 8mm                      | 2b                                                 |
| TV37M10                                   | TRI® Vent Implant Ø 3.75mm - L 10mm                     | 2b                                                 |
| TV37M11                                   | TRI® Vent Implant Ø 3.75mm - L 11.5mm                   | 2b                                                 |
| TV37M13                                   | TRI® Vent Implant Ø 3.75mm - L 13mm                     | 2b                                                 |
| TV37M16                                   | TRI® Vent Implant Ø 3.75mm - L 16mm                     | 2b                                                 |
| TV41M06                                   | TRI® Vent Implant Ø 4.1mm - L 6.5mm                     | 2b                                                 |
| TV41M08                                   | TRI® Vent Implant Ø 4.1mm - L 8mm                       | 2b                                                 |
| TV41M10                                   | TRI® Vent Implant Ø 4.1mm - L 10mm                      | 2b                                                 |
| TV41M11                                   | TRI® Vent Implant Ø 4.1mm - L 11.5mm                    | 2b                                                 |
| TV41M13                                   | TRI® Vent Implant Ø 4.1mm - L 13mm                      | 2b                                                 |
| TV41M16                                   | TRI® Vent Implant Ø 4.1mm - L 16mm                      | 2b                                                 |
| TV47M06                                   | TRI® Vent Implant Ø 4.7mm - L 6.5mm                     | 2b                                                 |
| TV47M08                                   | TRI® Vent Implant Ø 4.7mm - L 8mm                       | 2b                                                 |
| TV47M10                                   | TRI® Vent Implant Ø 4.7mm - L 10mm                      | 2b                                                 |
| TV47M11                                   | TRI® Vent Implant Ø 4.7mm - L 11.5mm                    | 2b                                                 |
| TV47M13                                   | TRI® Vent Implant Ø 4.7mm - L 13mm                      | 2b                                                 |
| TV47M16                                   | TRI® Vent Implant Ø 4.7mm - L 16mm                      | 2b                                                 |
| <b>TRI® Dental Implants - TRI®-Narrow</b> |                                                         |                                                    |
| TN33M10                                   | TRI® Narrow Implant Ø 3.3mm - L 10mm                    | 2b                                                 |
| TN33M11                                   | TRI® Narrow Implant Ø 3.3mm - L 11.5mm                  | 2b                                                 |
| TN33M13                                   | TRI® Narrow Implant Ø 3.3mm - L 13mm                    | 2b                                                 |
| TN33M16                                   | TRI® Narrow Implant Ø 3.3mm - L 16mm                    | 2b                                                 |
| <b>TRI® Dental Implants - TRI®-Octa</b>   |                                                         |                                                    |
| TO37M08                                   | TO Implant - Ø 3.75mm - 4.8mmP - L 8mm - incl. TOSCS    | 2b                                                 |
| TO37M10                                   | TO Implant - Ø 3.75mm - 4.8mmP - L 10mm - incl. TOSCS   | 2b                                                 |
| TO37M11                                   | TO Implant - Ø 3.75mm - 4.8mmP - L 11.5mm - incl. TOSCS | 2b                                                 |
| TO37M13                                   | TO Implant - Ø 3.75mm - 4.8mmP - L 13mm - incl. TOSCS   | 2b                                                 |
| TO41M06                                   | TO Implant - Ø 4.1mm - 4.8mmP - L 6.5mm - incl. TOSCS   | 2b                                                 |
| TO41M08                                   | TO Implant - Ø 4.1mm - 4.8mmP - L 8mm - incl. TOSCS     | 2b                                                 |
| TO41M10                                   | TO Implant - Ø 4.1mm - 4.8mmP - L 10mm - incl. TOSCS    | 2b                                                 |
| TO41M11                                   | TO Implant - Ø 4.1mm - 4.8mmP - L 11.5mm - incl. TOSCS  | 2b                                                 |
| TO41M13                                   | TO Implant - Ø 4.1mm - 4.8mmP - L 13mm - incl. TOSCS    | 2b                                                 |
| TO47M06                                   | TO Implant - Ø 4.7mm - 4.8mmP - L 6.5mm - incl. TOSCS   | 2b                                                 |



| Article No.                                | Name                                                   | Class According to Annex IX of directive 93/42/EEC |
|--------------------------------------------|--------------------------------------------------------|----------------------------------------------------|
| TO47M08                                    | TO Implant - Ø 4.7mm - 4.8mmP - L 8mm - incl. TOSCS    | 2b                                                 |
| TO47M10                                    | TO Implant - Ø 4.7mm - 4.8mmP - L 10mm - incl. TOSCS   | 2b                                                 |
| TO47M11                                    | TO Implant - Ø 4.7mm - 4.8mmP - L 11.5mm - incl. TOSCS | 2b                                                 |
| TO47M13                                    | TO Implant - Ø 4.7mm - 4.8mmP - L 13mm - incl. TOSCS   | 2b                                                 |
| <b>TRI® Dental Implants – TRI®-matrix®</b> |                                                        |                                                    |
| BLM-37-08-P37                              | Bone Level Matrix® Implant Ø 3.75mm - L 8mm-P37        | 2b                                                 |
| BLM-37-10-P37                              | Bone Level Matrix® Implant Ø 3.75mm - L 10mm-P37       | 2b                                                 |
| BLM-37-11-P37                              | Bone Level Matrix® Implant Ø 3.75mm - L 11.5mm-P37     | 2b                                                 |
| BLM-37-13-P37                              | Bone Level Matrix® Implant Ø 3.75mm - L 13mm-P37       | 2b                                                 |
| BLM-37-16-P37                              | Bone Level Matrix® Implant Ø 3.75mm - L 16mm-P37       | 2b                                                 |
| BLM-41-06-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 6.5mm-P37       | 2b                                                 |
| BLM-41-08-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 8mm-P37         | 2b                                                 |
| BLM-41-10-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 10mm-P37        | 2b                                                 |
| BLM-41-11-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 11.5mm-P37      | 2b                                                 |
| BLM-41-13-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 13mm-P37        | 2b                                                 |
| BLM-41-16-P37                              | Bone Level Matrix® Implant Ø 4.1mm - L 16mm-P37        | 2b                                                 |
| BLM-47-06-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 6.5mm-P45       | 2b                                                 |
| BLM-47-08-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 8mm-P45         | 2b                                                 |
| BLM-47-10-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 10mm-P45        | 2b                                                 |
| BLM-47-11-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 11.5mm-P45      | 2b                                                 |
| BLM-47-13-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 13mm-P45        | 2b                                                 |
| BLM-47-16-P45                              | Bone Level Matrix® Implant Ø 4.7mm - L 16mm-P45        | 2b                                                 |
| TLM-33-10-P37                              | Tissue Level Matrix® Implant Ø 3.3mm - L 10mm - P37    | 2b                                                 |
| TLM-33-11-P37                              | Tissue Level Matrix® Implant Ø 3.3mm - L 11.5mm - P37  | 2b                                                 |
| TLM-33-13-P37                              | Tissue Level Matrix® Implant Ø 3.3mm - L 13mm - P37    | 2b                                                 |
| TLM-37-08-P37                              | Tissue Level Matrix® Implant Ø 3.75mm - L 8mm - P37    | 2b                                                 |
| TLM-37-10-P37                              | Tissue Level Matrix® Implant Ø 3.75mm - L 10mm - P37   | 2b                                                 |
| TLM-37-11-P37                              | Tissue Level Matrix® Implant Ø 3.75mm - L 11.5mm - P37 | 2b                                                 |
| TLM-37-13-P37                              | Tissue Level Matrix® Implant Ø 3.75mm - L 13mm - P37   | 2b                                                 |
| TLM-37-16-P37                              | Tissue Level Matrix® Implant Ø 3.75mm - L 16mm - P37   | 2b                                                 |
| TLM-41-06-P37                              | Tissue Level Matrix® Implant Ø 4.1mm - L 6.5mm - P37   | 2b                                                 |
| TLM-41-08-P37                              | Tissue Level Matrix® Implant Ø 4.1mm - L 8mm -P37      | 2b                                                 |
| TLM-41-10-P37                              | Tissue Level Matrix® Implant Ø 4.1mm - L 10mm - P37    | 2b                                                 |

| Article No.                             | Name                                                   | Class According to Annex IX of directive 93/42/EEC |
|-----------------------------------------|--------------------------------------------------------|----------------------------------------------------|
| TLM-41-11-P37                           | Tissue Level Matrix® Implant Ø 4.1mm - L 11.5mm - P37  | 2b                                                 |
| TLM-41-13-P37                           | Tissue Level Matrix® Implant Ø 4.1mm - L 13mm - P37    | 2b                                                 |
| TLM-41-16-P37                           | Tissue Level Matrix® Implant Ø 4.1mm - L 16mm - P37    | 2b                                                 |
| TLM-37-08-P45                           | Tissue Level Matrix® Implant Ø 3.75mm - L 8mm - P45    | 2b                                                 |
| TLM-37-10-P45                           | Tissue Level Matrix® Implant Ø 3.75mm - L 10mm - P45   | 2b                                                 |
| TLM-37-11-P45                           | Tissue Level Matrix® Implant Ø 3.75mm - L 11.5mm - P45 | 2b                                                 |
| TLM-37-13-P45                           | Tissue Level Matrix® Implant Ø 3.75mm - L 13mm - P45   | 2b                                                 |
| TLM-37-16-P45                           | Tissue Level Matrix® Implant Ø 3.75mm - L 16mm - P45   | 2b                                                 |
| TLM-41-06-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 6.5mm - P45   | 2b                                                 |
| TLM-41-08-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 8mm - P45     | 2b                                                 |
| TLM-41-10-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 10mm - P45    | 2b                                                 |
| TLM-41-11-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 11.5mm - P45  | 2b                                                 |
| TLM-41-13-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 13mm - P45    | 2b                                                 |
| TLM-41-16-P45                           | Tissue Level Matrix® Implant Ø 4.1mm - L 16mm - P45    | 2b                                                 |
| TLM-47-06-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 6.5mm - P45   | 2b                                                 |
| TLM-47-08-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 8mm - P45     | 2b                                                 |
| TLM-47-10-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 10mm - P45    | 2b                                                 |
| TLM-47-11-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 11.5mm - P45  | 2b                                                 |
| TLM-47-13-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 13mm - P45    | 2b                                                 |
| TLM-47-16-P45                           | Tissue Level Matrix® Implant Ø 4.7mm - L 16mm - P45    | 2b                                                 |
| <b>TRI® Dental Abutment - TRI®-Vent</b> |                                                        |                                                    |
| TVHC35-30                               | Healing Collar - Ø 3.5mm - 3mm                         | 2b                                                 |
| TVHC35-45                               | Healing Collar - Ø 3.5mm - 4.5mm                       | 2b                                                 |
| TVHC35-60                               | Healing Collar - Ø 3.5mm - 6mm                         | 2b                                                 |
| TVHC35-60-A                             | Healing Collar - Aesthetic - Ø 3.5mm - 6mm             | 2b                                                 |
| TVHC50-30                               | Healing Collar - Ø 5mm - 3mm                           | 2b                                                 |
| TVHC50-45                               | Healing Collar - Ø 5mm - 4.5mm                         | 2b                                                 |
| TVHC50-60                               | Healing Collar - Ø 5mm - 6mm                           | 2b                                                 |
| TVHC50-60-A                             | Healing Collar - Aesthetic - Ø 5mm - 6mm               | 2b                                                 |
| TV10-35-ITC                             | 2in1 Impression Abutment - Ø 3.5mm                     | 2b                                                 |
| TV10-50-ITC                             | 2in1 Impression Abutment - Ø 5.0mm                     | 2b                                                 |
| TV10-EHA-50                             | Esthetic Healing Abutment 5.0mm                        | 2b                                                 |
| TV10-EHA-70                             | Esthetic Healing Abutment 7.0mm                        | 2b                                                 |

| Article No.  | Name                                                                     | Class According to Annex IX of directive 93/42/EEC |
|--------------|--------------------------------------------------------------------------|----------------------------------------------------|
| TV10-PTA     | Temporary Abutment Straight                                              | 2b                                                 |
| TV10-TTA     | Temporary Abutment Straight, Ø 4.5mm                                     | 2b                                                 |
| TV10-35-F    | Straight Abutment - Friction incl. RS-TV10 - Ø 3.5mm                     | 2b                                                 |
| TV10-41-F    | Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 1mm     | 2b                                                 |
| TV10-43-F    | Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 3mm     | 2b                                                 |
| TV10-50-F    | Straight Abutment - Friction incl. RS-TV10 - Ø 5mm                       | 2b                                                 |
| TV20-41-F    | Contour Abutment - Angled - Friction incl. RS-TV10 - Ø 4.5mm - 1mm - 17° | 2b                                                 |
| TV20-43-F    | Contour Abutment - Angled - Friction incl. RS-TV10 - Ø 4.5mm - 3mm - 17° | 2b                                                 |
| TV20-50-F    | Angled Abutment - Standard - Friction incl. RS-TV20 - Ø 5mm - 20°        | 2b                                                 |
| TV30-50-F    | Gold Castable Abutment - Friction incl. RS-TV10 - Ø 5mm                  | 2b                                                 |
| TV35-50      | NEM Castable Abutment incl. RS-TV20 - Ø 5mm                              | 2b                                                 |
| TV40-01      | Screw Retained Abutment - Straight - Ø 4.5mm - 1mm                       | 2b                                                 |
| TV40-02      | Screw Retained Abutment - Straight - Ø 4.5mm - 2mm                       | 2b                                                 |
| TV40-04      | Screw Retained Abutment - Straight - Ø 4.5mm - 4mm                       | 2b                                                 |
| TV40-06      | Screw Retained Abutment - Straight - Ø 4.5mm - 6mm                       | 2b                                                 |
| TV50-17      | Screw Retained Abutment - Angulated 17° - Ø 4.5mm - 4.7mm                | 2b                                                 |
| TV50-30      | Screw Retained Abutment - Angulated 30° - Ø 4.5mm - 4.7mm                | 2b                                                 |
| TV50-30-S    | Screw Retained Abutment - Angulated 30°-Short – Ø 4.5mm                  | 2b                                                 |
| TV60-02      | Ball Abutment incl. CAHL - Ø 4.5mm - 2mm                                 | 2b                                                 |
| TV60-04      | Ball Abutment incl. CAHL - Ø 4.5mm - 4mm                                 | 2b                                                 |
| TV70-07-F    | TRI®-Vent TRI®-Base Engaging, 4.5mmD, 0.7mm Cuff                         | 2b                                                 |
| TV70-07-NE   | TRI®-Vent TRI®-Base Non Engaging, 4,5mmD, 0.7mm Cuff                     | 2b                                                 |
| TV70-20-F    | TRI®-Vent TRI®-Base Engaging, 4.5mmD, 2.0 mm Cuff                        | 2b                                                 |
| TV70-20-NE   | TRI®-Vent TRI®-Base Non-Engaging, 4.5mmD, 2.0 mm Cuff                    | 2b                                                 |
| TV70-Blank-F | TRI®-Vent Milling Blank, 11.5mmD, 0.7mm Cuff                             | 2b                                                 |
| TV70-SCAN    | Scan Abutment 3G                                                         | 2b                                                 |
| RS-TV10      | Replacement Retaining Screw                                              | 2b                                                 |
| TVSCS        | Surgical Cover Screw - Ø 3.5mm                                           | 2b                                                 |
| TVSCS-01     | Surgical Cover Screw - Ø 3.5mm-1mm                                       | 2b                                                 |
| TVSCS-02     | Surgical Cover Screw - Ø 3.5mm-2mm                                       | 2b                                                 |
| TVSCS-SL     | Surgical Cover Screw for Sinus Lift - Ø 5.2mm                            | 2b                                                 |
| RS-TV20      | Replacement Retaining Screw                                              | 2b                                                 |
| TV40-Scan    | Multi Unit Scan Body                                                     | 2b                                                 |

| Article No.                               | Name                                                                     | Class According to Annex IX of directive 93/42/EEC |
|-------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| RS-PCC                                    | Replacement Retaining Screw for PCC                                      | 2b                                                 |
| RS-TTA                                    | Replacement Retaining Screw for TTA                                      | 2b                                                 |
| TTA                                       | Titanium Temporary Abutment incl. RS-TTA                                 | 2b                                                 |
| RS-MUA-D-4                                | Replacement Retaining Screw for MUA - 4                                  | 2b                                                 |
| <b>TRI® Dental Abutment - TRI®-Narrow</b> |                                                                          |                                                    |
| TNHC35-30                                 | Healing Collar - Ø 3,5mm - 3mm - blue                                    | 2b                                                 |
| TNHC35-45                                 | Healing Collar - Ø 3,5mm - 4.5mm - blue                                  | 2b                                                 |
| TNHC35-60                                 | Healing Collar - Ø 3,5mm - 6mm - blue                                    | 2b                                                 |
| TNHC35-60-A                               | Healing Collar - Aesthetic - Ø 3,5mm - 6mm - blue                        | 2b                                                 |
| TNHC45-30                                 | Healing Collar - Ø 4,5mm - 3mm - blue                                    | 2b                                                 |
| TNHC45-50                                 | Healing Collar - Ø 4,5mm - 5mm - blue                                    | 2b                                                 |
| TN10-PTA                                  | Temporary Abutment, Straight                                             | 2b                                                 |
| TN10-35-F                                 | Straight Abutment - Friction incl. RS-TN10 - Ø 3,5mm                     | 2b                                                 |
| TN10-41-F                                 | Narrow Contour Abutment, Straight TRI-Friction 1mm                       | 2b                                                 |
| TN10-43-F                                 | Narrow Contour Abutment, Straight TRI-Friction 3mm                       | 2b                                                 |
| TN20-41-F                                 | Contour Abutment - Angled - Friction incl. RS-TN10 - Ø 4.0mm - 1mm - 17° | 2b                                                 |
| TN20-43-F                                 | Contour Abutment - Angled - Friction incl. RS-TN10 - Ø 4.0mm - 3mm - 17° | 2b                                                 |
| TN20-45-F                                 | Angled Abutment - Standard - Friction incl. RS-TN10 - Ø 4.5mm - 20°      | 2b                                                 |
| TN30-45-F                                 | Gold Castable Abutment -Friction incl. RS-TN10 - Ø 4.5mm                 | 2b                                                 |
| TN40-02                                   | Screw Retained Abutment - Straight - Ø 4,5mm - 2mm                       | 2b                                                 |
| TN40-04                                   | Screw Retained Abutment - Straight - Ø 4,5mm - 4mm                       | 2b                                                 |
| TN60-02                                   | Ball Abutment incl. CAHL - Ø 4.5mm - 2mm                                 | 2b                                                 |
| TN60-04                                   | Ball Abutment incl. CAHL - Ø 4.5mm - 4mm                                 | 2b                                                 |
| TN70-07-F                                 | TRI®-Narrow TRI®-Base Engaging, 4.2mmD, 0.7mm Cuff                       | 2b                                                 |
| TN70-07-NE                                | TRI®-Narrow TRI®-Base Non-Engaging, 4.2mmD, 0.7 mm Cuff                  | 2b                                                 |
| TN70-Blank-F                              | TRI®-Narrow Milling Blank, 11.5mmD, 0.7mm Cuff                           | 2b                                                 |
| TN70-Scan                                 | TRI®-Narrow Scan Body                                                    | 2b                                                 |
| HC-SRAS                                   | Healing Cap for Screw-Retained Abutment - Straight                       | 2b                                                 |
| RS-TN10                                   | Replacement Retaining Screw - blue                                       | 2b                                                 |
| RS-TN20                                   | Replacement Retaining Screw for TN20 for TN20                            | 2b                                                 |
| RS-TTAL                                   | Replacement Retaining Screw for TTA - long                               | 2b                                                 |
| TNSCS                                     | Surgical Cover Screw - Ø 3.2mm                                           | 2b                                                 |

| Article No.                                | Name                                                                 | Class According to Annex IX of directive 93/42/EEC |
|--------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------|
| HC-SRAS-H                                  | Healing Cap for Screw-Retained Abutment-High - Straight              | 2b                                                 |
| <b>TRI® Dental Abutment - TRI®-Octa</b>    |                                                                      |                                                    |
| TOHC51-15                                  | TO Healing Collar - Ø 5.1mm - Height 1.5mm                           | 2b                                                 |
| TOHC51-30                                  | TO Healing Collar - Ø 5.1mm - Height 3mm                             | 2b                                                 |
| TO10-51-ITC                                | TRI® Octa 2in1 Impression Abutment - Ø 5.1mm                         | 2b                                                 |
| TO10-PTA                                   | TO Temporary Abutment - Ø 5,1mm incl. RS-TO                          | 2b                                                 |
| TO10-35-F                                  | TO Straight Abutment - Friction incl. RS-TO - Ø 3.5mm                | 2b                                                 |
| TO10-51-F                                  | TO Straight Abutment - Friction incl. RS-TO - Ø 5.1mm                | 2b                                                 |
| TO20-51-F                                  | TO Angled Abutment - Standard - Friction incl. RS-TO - Ø 5.1mm - 20° | 2b                                                 |
| TO40-16                                    | TO Screw Retained Abutment - Straight - Ø 4.5mm - 1.6mm              | 2b                                                 |
| TO40-30                                    | TO Screw Retained Abutment - Straight - Ø 4.5mm - 3mm                | 2b                                                 |
| TO60-16                                    | Ball Abutment incl. CAHL - Ø 4.5mm - 1.6mm                           | 2b                                                 |
| TO60-30                                    | Ball Abutment incl. CAHL - Ø 4.5mm - 3mm                             | 2b                                                 |
| TO70-07-F                                  | TRI®-Octa TRI®-Base Engaging, 5.1 mmD                                | 2b                                                 |
| TO70-07-NE                                 | TRI®-Octa TRI®-Base Non-Engaging, 5.1 mmD                            | 2b                                                 |
| TO70-Blank-F                               | TRI®-Octa Milling Blank, 11.5mmD                                     | 2b                                                 |
| TO70-Scan                                  | TO Scan Abutment                                                     | 2b                                                 |
| RS-TO                                      | TO Replacement Retaining Screw                                       | 2b                                                 |
| TOSCS                                      | TO Surgical Cover Screw                                              | 2b                                                 |
| <b>TRI® Dental Abutment - TRI®-matrix®</b> |                                                                      |                                                    |
| M-HC-37-15-P37                             | Matrix®-Healing Collar - Ø 3.7mm - 1.5mm-P37                         | 2b                                                 |
| M-HC-37-30-P37                             | Matrix®-Healing Collar - Ø 3.7mm - 3mm-P37                           | 2b                                                 |
| M-HC-37-45-P37                             | Matrix®-Healing Collar - Ø 3.7mm - 4.5mm-P37                         | 2b                                                 |
| M-HC-37-60-P37                             | Matrix®-Healing Collar - Ø 3.7mm - 6mm-P37                           | 2b                                                 |
| M-HC-50-30-P37                             | Matrix®-Healing Collar - Ø 5mm - 3mm-P37                             | 2b                                                 |
| M-HC-50-45-P37                             | Matrix®-Healing Collar - Ø 5mm - 4.5mm-P37                           | 2b                                                 |
| M-HC-50-60-P37                             | Matrix®-Healing Collar - Ø 5mm - 6mm-P37                             | 2b                                                 |
| M-HC-45-15-P45                             | Matrix®-Healing Collar - Ø 4.5mm - 1.5mm-P45                         | 2b                                                 |
| M-HC-45-30-P45                             | Matrix®-Healing Collar - Ø 4.5mm - 3mm-P45                           | 2b                                                 |
| M-HC-45-45-P45                             | Matrix®-Healing Collar - Ø 4.5mm - 4.5mm -P45                        | 2b                                                 |
| M-HC-45-60-P45                             | Matrix®-Healing Collar - Ø 4.5mm - 6mm-P45                           | 2b                                                 |
| BLM-Prov-EN-P37                            | BL-Temporary Abutment Straight, Ø 4.9mm-EN-P37                       | 2b                                                 |
| BLM-Prov-NE-P37                            | BL-Temporary Abutment Straight, Ø 4.9mm-NE-P37                       | 2b                                                 |
| BLM-Prov-EN-P45                            | BL-Temporary Abutment Straight, Ø 4.9mm-EN-P45                       | 2b                                                 |

| Article No.     | Name                                                       | Class According to Annex IX of directive 93/42/EEC |
|-----------------|------------------------------------------------------------|----------------------------------------------------|
| BLM-Prov-NE-P45 | BL-Temporary Abutment Straight, Ø 4.9mm-NE-P45             | 2b                                                 |
| BLM-05-37-P37   | BL-Direct Transfer Component incl. RS-BLM-05 - Ø3.7mm-P37  | 2a                                                 |
| BLM-05-50-P37   | BL-Direct Transfer Component incl. RS-BLM-05 - Ø 5mm-P37   | 2a                                                 |
| BLM-05-45-P45   | BL-Direct Transfer Component incl. RS-BLM-05 - Ø 4.5mm-P45 | 2a                                                 |
| RS-BLM-05       | BL-Direct Transfer Retaining Screw                         | 2a                                                 |
| TLM-Prov-EN-P37 | TL-Temporary Abutment Straight, Ø 4.2mm-EN-P37             | 2b                                                 |
| TLM-Prov-NE-P37 | TL-Temporary Abutment Straight, Ø 4.2mm-NE-P37             | 2b                                                 |
| TLM-Prov-EN-P45 | TL-Temporary Abutment Straight, Ø 5.1mm-EN-P45             | 2b                                                 |
| TLM-Prov-NE-P45 | TL-Temporary Abutment Straight, Ø 5.1mm-NE-P45             | 2b                                                 |
| TLM-05-37-P37   | TL-Direct Transfer Component incl. RS-TLM-05 - Ø 4.5mm-P37 | 2a                                                 |
| TLM-05-45-P45   | TL-Direct Transfer Component incl. RS-TLM-05 - Ø 5mm-P45   | 2a                                                 |
| RS-TLM-05       | TL-Direct Transfer Retaining Screw                         | 2a                                                 |
| M-70-07-EN-P37  | Matrix®-Base Engaging, 4.5mmD, 0.7mm Cuff-EN-P37           | 2b                                                 |
| M-70-07-NE-P37  | Matrix®-Base Non-Engaging, 4.5mmD, 0.7mm Cuff-EN-P37       | 2b                                                 |
| M-70-07-EN-P45  | Matrix®-Base Engaging, 4.8mmD, 0.7mm Cuff-EN-P45           | 2b                                                 |
| M-70-07-NE-P45  | Matrix®-Base Non-Engaging, 4.8mmD, 0.7mm Cuff-NE-P45       | 2b                                                 |
| M-CS-P37        | Matrix®-Surgical Cover Screw for Sinus Lift - Ø 3.7mm-P37  | 2b                                                 |
| M-CS-P45        | Matrix®-Surgical Cover Screw for Sinus Lift - Ø 4.6mm-P45  | 2b                                                 |
| SCRW-2.25       | Replacement Retaining Screw                                | 2b                                                 |
| SCRW-2.6        | Replacement Retaining Screw                                | 2b                                                 |
| SCRW-2.8        | Replacement Retaining Screw                                | 2b                                                 |
| SCRW-3.25       | Replacement Retaining Screw                                | 2b                                                 |

| Article No.  | Name                             | Class According to Annex IX of directive 93/42/EEC |
|--------------|----------------------------------|----------------------------------------------------|
| M-SCRW-2.25  | Replacement Retaining Screw      | 2b                                                 |
| M-SCRW-2.6   | Replacement Retaining Screw      | 2b                                                 |
| M-SCRW-2.8   | Replacement Retaining Screw      | 2b                                                 |
| M-SCRW-2.8-L | Replacement Retaining Screw-Long | 2b                                                 |
| M-SCRW-3.25  | Replacement Retaining Screw      | 2b                                                 |
| M-MUA-P37    | Matrix® Multiunit Abutment P37   | 2b                                                 |
| M-MUA-P45    | Matrix® Multiunit Abutment P45   | 2b                                                 |



|                         |                                                            |
|-------------------------|------------------------------------------------------------|
| Title                   | EC Declaration of conformity implants and abutments_DQS_10 |
| File name               | EC Declaration of...tments_DQS_10.doc                      |
| Document ID             | 52251bf820fb51e75b3c986766d2c910418ca3e4                   |
| Audit trail date format | DD / MM / YYYY                                             |
| Status                  | ● Signed                                                   |

## Document History



SENT

**19 / 07 / 2023**

14:27:41 UTC+2

Sent for signature to Sandro Venanzoni (sv@tri.swiss) from  
veronique.arnegger@tri-implants.swiss  
IP: 87.140.85.217



VIEWED

**19 / 07 / 2023**

14:31:32 UTC+2

Viewed by Sandro Venanzoni (sv@tri.swiss)  
IP: 213.55.227.189



SIGNED

**19 / 07 / 2023**

14:31:42 UTC+2

Signed by Sandro Venanzoni (sv@tri.swiss)  
IP: 213.55.227.189



COMPLETED

**19 / 07 / 2023**

14:31:42 UTC+2

The document has been completed.

**EC Declaration of Conformity**  
EC Directive 93/42/EEC Annex II, excluded point 4  
**Full Quality Assurance System**  
**Medical Devices**

Registration No.: 535987 MR2  
Certification No.: 170739372 (issued 2019-12-01)

Manufacturer: **TRI® Dental Implants Int. AG**  
**Bösch 80A**  
**CH-6331 Hünenberg**  
**Switzerland**

Scope: TRI® Dental Implant System:  
• TRI® Dental Instruments

This declaration of conformity is valid until 2024-05-26 and remains valid subject to satisfactory surveillance audits.

We, the company TRI® Dental Implants Int. AG, hereby declare, that we are exclusively responsible for the declaration of conformity and that the distributed CE marked products, specified in the annex 1 product list, are in compliance with the Essential Requirements as defined by the provisions of Council Directive 93/42/EEC Annex I.

The medical devices listed above have been classified according to the classification rules according to Council Directive 93/42/EEC Annex IX and have met all the applicable conformity assessment elements. The conformity assessment procedure has been applied according to Council Directive 93/42/EEC Annex II, excluded point 4.

Notified Body:  
DQS 0297  
DQS Medizinprodukte GmbH  
August-Schanz-Str. 21  
60433 Frankfurt am Main,  
Germany

As part of the conformity the norms of the CE registration are fulfilled:

REC\_Regulatory List\_TRI Dental Implant System\_08.

Sandro Venanzoni  
Hünenberg, 2023-07-21



---

Sandro Venanzoni - CTO

## EC Declaration of Conformity

### Annex 1: Product List

| Article No.  | Name                                                | Class According to Annex IX of directive 93/42/EEC |
|--------------|-----------------------------------------------------|----------------------------------------------------|
| PD-ISO-L     | TRI® ISO Prosthetic Driver - Long                   | 2a                                                 |
| PD-ISO-S     | TRI® ISO Prosthetic Driver - Short                  | 2a                                                 |
| PD-ISO-L-Ang | TRI® – Prosthetic Driver Angled-Long                | 2a                                                 |
| DBD-3.7L     | TV 3,75 Dense Bone Drill - Long - Ø 2,9 - Ø 3,6mm   | 2a                                                 |
| DBD-3.7M     | TV 3,75 Dense Bone Drill - Medium - Ø 2,9 - Ø 3,6mm | 2a                                                 |
| DBD-4.1L     | TV 4,1 Dense Bone Drill - Long - Ø 3,2 - Ø 3,9mm    | 2a                                                 |
| DBD-4.1M     | TV 4,1 Dense Bone Drill - Medium - Ø 3,2 - Ø 3,9mm  | 2a                                                 |
| DBD-4.7L     | TV 4,7 Dense Bone Drill - Long - Ø 3,8 - Ø 4,5mm    | 2a                                                 |
| DBD-4.7M     | TV 4,7 Dense Bone Drill - Medium - Ø 3,8 - Ø 4,5mm  | 2a                                                 |
| LD           | Lance Drill                                         | 2a                                                 |
| ND-L         | TRI® Narrow Implant Driver Long                     | 2a                                                 |
| ND-S         | TRI® Narrow Implant Driver Short                    | 2a                                                 |
| OD-L         | TRI® Octa Implant Driver Long                       | 2a                                                 |
| OD-S         | TRI® Octa Implant Driver Short                      | 2a                                                 |
| SBD-3.7L     | TV 3,75 Soft Bone Drill - Long - Ø 2,7 - Ø 3,1mm    | 2a                                                 |
| SBD-3.7M     | TV 3,75 Soft Bone Drill - Medium - Ø 2,7 - Ø 3,1mm  | 2a                                                 |
| SBD-3.7S     | TV 3,75 Soft Bone Drill - Short - Ø 2,7 - Ø 3,1mm   | 2a                                                 |
| SBD-4.1L     | TV 4,1 Soft Bone Drill - Long - Ø 3 - Ø 3,4mm       | 2a                                                 |
| SBD-4.1M     | TV 4,1 Soft Bone Drill - Medium - Ø 3 - Ø 3,4mm     | 2a                                                 |
| SBD-4.1S     | TV 4,1 Soft Bone Drill - Short - Ø 3 - Ø 3,4mm      | 2a                                                 |
| SBD-4.7L     | TV 4,7 Soft Bone Drill - Long - Ø 3,6 - Ø 4,0mm     | 2a                                                 |
| SBD-4.7M     | TV 4,7 Soft Bone Drill - Medium - Ø 3,6 - Ø 4,0mm   | 2a                                                 |
| SBD-4.7S     | TV 4,7 Soft Bone Drill - Short - Ø 3,6 - Ø 4,0mm    | 2a                                                 |
| TAP3.3       | TRI-Narrow Tap Drill - Ø 3.3mm                      | 2a                                                 |
| TAP3.7       | TRI-Vent TAP Drill - Ø 3,75mm                       | 2a                                                 |
| TAP4.1       | TRI-Vent TAP Drill - Ø 4,1mm                        | 2a                                                 |
| TAP4.7       | TRI-Vent Tap Drill - Ø 4.7mm                        | 2a                                                 |
| TND-3.3L     | TRI-Narrow Final Drill - Ø 2.4 - Ø 2.8mm            | 2a                                                 |
| TND-3.3M     | TRI-Narrow Final Drill - Medium - Ø 2.4 - Ø 2.8mm   | 2a                                                 |
| TPD-2.3L     | Pilot Drill - Ø 2.3 - long                          | 2a                                                 |
| TPD-2.3M     | Pilot Drill - Ø 2.3 - Medium                        | 2a                                                 |
| TPD-2.3S     | Pilot Drill - Ø 2.3 - short                         | 2a                                                 |
| VD-L         | TRI® Vent Implant Driver Long                       | 2a                                                 |
| VD-S         | TRI® Vent Implant Driver Short                      | 2a                                                 |
| MD-L-ISO     | Matrix® Implant Driver Long                         | 2a                                                 |
| MD-S-ISO     | Matrix® Implant Driver Short                        | 2a                                                 |
| RB-2.3       | Roundbur for Handpiece                              | 2a                                                 |

|                         |                                                          |
|-------------------------|----------------------------------------------------------|
| Title                   | EC Declaration of conformity instruments class 2a_DQS_09 |
| File name               | EC Declaration of...ass 2a_DQS_09.doc                    |
| Document ID             | bce9c922a053b466ce0b4c882c6c0b5eb90a8f01                 |
| Audit trail date format | DD / MM / YYYY                                           |
| Status                  | ● Signed                                                 |

## Document History



**19 / 07 / 2023**  
14:26:01 UTC+2

Sent for signature to Sandro Venanzoni (sv@tri.swiss) from  
veronique.arnegger@tri-implants.swiss  
IP: 87.140.85.217



**19 / 07 / 2023**  
14:31:14 UTC+2

Viewed by Sandro Venanzoni (sv@tri.swiss)  
IP: 213.55.227.189



**19 / 07 / 2023**  
14:31:26 UTC+2

Signed by Sandro Venanzoni (sv@tri.swiss)  
IP: 213.55.227.189



COMPLETED

**19 / 07 / 2023**  
14:31:26 UTC+2

The document has been completed.