

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 Abutments

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_List_of_Standards_TRI_Dental_Implant_System_02.

Sandro Venanzoni
Hünenberg, 2020-12-07



Sandro Venanzoni - CTO

EC Declaration of Conformity Annex 1: Product List

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|-------------|--|--|
| TV37M08 | Ø 3.75mm - L 8mm | 2b |
| TV37M10 | Ø 3.75mm - L 10mm | 2b |
| TV37M11 | Ø 3.75mm - L 11.5mm | 2b |
| TV37M13 | Ø 3.75mm - L 13mm | 2b |
| TV37M16 | Ø 3.75mm - L 16mm | 2b |
| TV41M06 | Vent Implant Machined, Ø 4.1mm, L6mm w. TVSCS | 2b |
| TV41M08 | Ø 4.1mm - L 8mm | 2b |
| TV41M10 | Ø 4.1mm - L 10mm | 2b |
| TV41M11 | Ø 4.1mm - L 11.5mm | 2b |
| TV41M13 | Ø 4.1mm - L 13mm | 2b |
| TV41M16 | Ø 4.1mm - L 16mm | 2b |
| TV47M06 | Ø 4.7mm - L 6.5mm | 2b |
| TV47M08 | Ø 4.7mm - L 8mm | 2b |
| TV47M10 | Ø 4.7mm - L 10mm | 2b |
| TV47M11 | Ø 4.7mm - L 11.5mm | 2b |
| TV47M13 | Ø 4.7mm - L 13mm | 2b |
| TV47M16 | Ø 4.7mm - L 16mm | 2b |
| 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 |
| 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 |

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|--------------|---|--|
| 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 |
| TN33M10 | Ø 3.3mm - L 10mm | 2b |
| TN33M11 | Ø 3.3mm - L 11.5mm | 2b |
| TN33M13 | Ø 3.3mm - L 13mm | 2b |
| TN33M16 | Ø 3.3mm - L 16mm | 2b |
| 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 |
| TN10-35-ITC | TRI® Narrow 2in1 Impression Abutment - Ø 3.5mm | 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 |

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|--------------|--|--|
| 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 |
| 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 |
| 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 |
| TOHC51-15 | TO Healing Collar - Ø 5.1mm - Height 1.5mm | 2b |

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|---------------|--|--|
| 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 - Straigth - Ø 4.5mm - 1.6mm | 2b |
| TO40-30 | TO Screw Retained Abutment - Straigth - 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 |
| DTC-SRA | Direct Transfer Component for TV40 incl. DTRS-SRA | 2a |
| DTRS-SRA | Direct Transfer Retaining Screw | 2a |
| RS-PCC | Replacement Retaining Screw for PCC | 2b |
| RS-TTA | Replacement Retaining Screw for TTA | 2b |
| TTA | Titanium Temporary Abutment incl. RS-TTA | 2b |
| TV40-Scan | Multi Unit Scan Body | 2b |
| TV05-35 | Direct Transfer Component incl. DTRS - Ø 3.5mm | 2a |
| TV05-50 | Direct Transfer Component incl. DTRS - Ø 5mm | 2a |
| DTRS-TV05 | Direct Transfer Retaining Screw | 2a |
| TN05-35 | Direct Transfer Component incl. DTRS-TN05 Ø 3.5mm - blue | 2a |
| DTRS-TN05 | Direct Transfer Retaining Screw for TN05 - blue | 2a |
| TO05-51 | TO Direct Transfer Component incl. DTRS-TO05 - Ø 5.1mm | 2a |
| DTRS-TO05 | TO Replacement Screw for TO05-51 | 2a |
| 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 |

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|-----------------|---|--|
| 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 |
| 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 |
| BLM-Prov-NE-P45 | BL-Temporary Abutment Straight, Ø 4.9mm-NE-P45 | 2b |
| 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, 5mmD, 0.7mm Cuff-EN-P45 | 2b |
| M-70-07-NE-P45 | Matrix®-Base Non-Engaging, 5mmD, 0.7mm Cuff-NE-P45 | 2b |
| SCRW-3.25 | Replacement Retaining Screw | 2b |
| SCRW-2.8 | Replacement Retaining Screw | 2b |
| SCRW-2.25 | Replacement Retaining Screw | 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 |
| 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 |

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|-----------------|--|--|
| TLM-37-13-P37 | Tissue Level Matrix® Implant Ø 3.75mm - L 13mm - 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 |
| 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-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-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-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-Prov-EN-P37 | TL-Temporary Abutment Straight, Ø 4.9mm-EN-P37 | 2b |
| TLM-Prov-NE-P37 | TL-Temporary Abutment Straight, Ø 4.9mm-NE-P37 | 2b |
| TLM-Prov-EN-P45 | TL-Temporary Abutment Straight, Ø 4.9mm-EN-P45 | 2b |
| TLM-Prov-NE-P45 | TL-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-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 |
| HC-SRAS-H | Healing Cap for Screw-Retained Abutment-High - Straight | 2b |

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

We, the company

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 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.

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

REC_List_of_Standards_TRI_Dental_Implant_System_02.

Sandro Venanzoni

Hünenberg, 2020-12-07



Sandro Venanzoni - CTO

| Article Nr. | Name | Class According to Annex IX of directive 93/42/EEC |
|--------------|--|--|
| PD-ISO-L-Ang | TRI® – Prosthetic Driver Angled-Long | 1 |
| PD-L | TRI® – Prosthetic Driver for Ratchet - Long | 1 |
| PD-S | TRI® – Prosthetic Driver for Ratchet - Short | 1 |
| TORT | TRI® Octa– Abutment Removal Tool | 1 |
| TRT | TRI® – Removal Tool for Abutment | 1 |
| TW | TRI® – Torque Wrench - 10-45Ncm | 1 |
| TW-Adapter | TRI® – Torque Wrench Adapter | 1 |
| PP-L | TRI® – Parallel Pins - long | 1 |
| TDS10 | TRI® – Drill Stops - 10mm | 1 |
| TDS11 | TRI® – Drill Stops - 11.5mm | 1 |
| TDS13 | TRI® – Drill Stops - 13mm | 1 |
| TDS6 | TRI® – Drill Stops - 6mm | 1 |
| TDS6 | TRI® – Drill Stops - 8mm | 1 |
| TDS8 | TRI® – Drill Stops - 8mm | 1 |
| TPDS | TRI® – Guided Surgery Sleeve for TPD | 1 |
| VD-L-TW | TRI® Vent – Implant Driver Long for torque wrench | 1 |
| VD-S-TW | TRI® Vent – Implant Driver Short for torque wrench | 1 |

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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_List_of_Standards_TRI_Dental_Implant_System_02.

Sandro Venanzoni
Hünenberg, 2020-12-07



Sandro Venanzoni - CTO

EC Declaration of Conformity Annex 1: Product List

| Article Nr. | 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 |
| 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 |
| VTool-P37 | Matrix® Verification Tool-P37 | 2a |
| VTool-P45 | Matrix® Verification Tool-P45 | 2a |