

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_01.

Sandro Venanzoni
Hünenberg, 2019-12-03



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	TRI@-Vent – Implant - M-SBA -3.5- Ø 3.75mm - L 8mm	2b
TV37M10	TRI@-Vent – Implant - M-SBA -3.5- Ø 3.75mm - L 10mm	2b
TV37M11	TRI@-Vent – Implant -M-SBA -3.5- Ø 3.75mm - L 11.5mm	2b
TV37M13	TRI@-Vent – Implant - M-SBA -3.5- Ø 3.75mm - L 13mm	2b
TV37M16	TRI@-Vent – Implant --M-SBA -3.5- Ø 3.75mm - L 16mm	2b
TV41M06	TRI@-Vent – Implant -M-SBA -3.5- Ø 4.1mm - L 6.5mm	2b
TV41M08	TRI@-Vent – Implant -M-SBA -3.5- Ø 4.1mm - L 8mm	2b
TV41M10	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.1mm - L 10mm	2b
TV41M11	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.1mm - L 11.5mm	2b
TV41M13	TRI@-Vent – Implant --M-SBA -3.5- Ø 4.1mm - L 13mm	2b
TV41M16	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.1mm - L 16mm	2b
TV47M06	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.7mm - L 6.5mm	2b
TV47M08	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.7mm - L 8mm	2b
TV47M10	TRI@-Vent – Implant - M-SBA -3.5- Ø 4.7mm - L 10mm	2b
TV47M11	TRI@-Vent – Implant - - M-SBA -3.5- Ø 4.7mm - L 11.5mm	2b
TV47M13	TRI@-Vent – Implant -- M-SBA -3.5- Ø 4.7mm - L 13mm	2b
TV47M16	TRI@-Vent – Implant - - M-SBA -3.5- Ø 4.7mm - L 16mm	2b
TVHC35-30	TRI@-Vent – Healing Collar - Ø 3.5mm - 3mm	2b
TVHC35-45	TRI@-Vent – Healing Collar - Ø 3.5mm - 4.5mm	2b
TVHC35-60	TRI@-Vent – Healing Collar - Ø 3.5mm - 6mm	2b
TVHC35-60-A	TRI@-Vent – Healing Collar - Aesthetic - Ø 3.5mm - 6mm	2b
TVHC50-30	TRI@-Vent – Healing Collar - Ø 5mm - 3mm	2b
TVHC50-45	TRI@-Vent – Healing Collar - Ø 5mm - 4.5mm	2b
TVHC50-60	TRI@-Vent – Healing Collar - Ø 5mm - 6mm	2b
TVHC50-60-A	TRI@-Vent – Healing Collar - Aesthetic - Ø 5mm - 6mm	2b
TV10-35-ITC	TRI@-Vent – 2in1 Impression Abutment - Ø 3.5mm	2b
TV10-50-ITC	TRI@-Vent – 2in1 Impression Abutment - Ø 5.0mm	2b
TV10-EHA-50	TRI@-Vent – Esthetic Healing Abutment 5.0mm	2b
TV10-EHA-70	TRI@-Vent – Esthetic Healing Abutment 7.0mm	2b
TV10-PTA	TRI@-Vent – Temporary Abutment Straight	2b
TV10-35-F	TRI@-Vent – Straight Abutment - Friction incl. RS-TV10 - Ø 3.5mm	2b
TV10-41-F	TRI@-Vent – Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 1mm	2b
TV10-43-F	TRI@-Vent – Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 3mm	2b
TV10-50-F	TRI@-Vent – Straight Abutment - Friction incl. RS-TV10 - Ø 5mm	2b
TV20-41-F	TRI@-Vent – Contour Abutment - Angled - Friction incl. RS-TV10 - Ø 4.5mm - 1mm - 17°	2b
TV20-43-F	TRI@-Vent – Contour Abutment - Angled - Friction incl. RS-TV10 - Ø 4.5mm - 3mm - 17°	2b
TV20-50-F	TRI@-Vent – 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	TRI@-Vent – Gold Castable Abutment - Friction incl. RS-TV10 - Ø 5mm	2b
TV35-50	TRI@-Vent – NEM Castable Abutment incl. RS-TV20 - Ø 5mm	2b
TV40-01	TRI@-Vent – Screw Retained Abutment - Straigth - Ø 4.5mm - 1mm	2b
TV40-02	TRI@-Vent – Screw Retained Abutment - Straigth - Ø 4.5mm - 2mm	2b
TV40-04	TRI@-Vent – Screw Retained Abutment - Straigth - Ø 4.5mm - 4mm	2b
TV40-06	TRI@-Vent – Screw Retained Abutment - Straigth - Ø 4.5mm - 6mm	2b
TV50-17	TRI@-Vent – Screw Retained Abutment - Angulated 17° - Ø 4.5mm - 4.7mm	2b
TV50-30	TRI@-Vent – Screw Retained Abutment - Angulated 30° - Ø 4.5mm - 4.7mm	2b
TV60-02	TRI@-Vent – Ball Abutment incl. CAHL - Ø 4.5mm - 2mm	2b
TV60-04	TRI@-Vent – 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	TRI@-Vent – Scan Abutment 3G	2b
RS-TV10	TRI@-Vent – Replacement Retaining Screw	2b
TVSCS	TRI@-Vent – Surgical Cover Screw - Ø 3.5mm	2b
TVSCS-1	TRI@-Vent – Surgical Cover Screw - Ø 3.5mm-1mm	2b
TVSCS-2	TRI@-Vent – Surgical Cover Screw - Ø 3.5mm-2mm	2b
TVSCS-SL	TRI@-Vent – Surgical Cover Screw for Sinus Lift - Ø 5.2mm	2b
RS-TV20	TRI@-Vent – Replacement Retaining Screw	2b
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
TNHC35-30	TRI@-Narrow – Healing Collar - Ø 3,5mm - 3mm - blue	2b
TNHC35-45	TRI@-Narrow – Healing Collar - Ø 3,5mm - 4.5mm - blue	2b
TNHC35-60	TRI@-Narrow – Healing Collar - Ø 3,5mm - 6mm - blue	2b
TNHC35-60-A	TRI@-Narrow – Healing Collar - Aesthetic - Ø 3,5mm - 6mm - blue	2b
TNHC45-30	TRI@-Narrow – Healing Collar - Ø 4,5mm - 3mm - blue	2b
TNHC45-50	TRI@-Narrow – Healing Collar - Ø 4,5mm - 5mm - blue	2b
TN10-35-ITC	TRI@-Narrow – TRI@ Narrow 2in1 Impression Abutment - Ø 3.5mm	2b

Article Nr.	Name	Class According to Annex IX of directive 93/42/EEC
TN10-PTA	TRI@-Narrow – Temporary Abutment, Straight	2b
TN10-35-F	TRI@-Narrow – Straight Abutment - Friction incl. RS-TN10 - Ø 3,5mm	2b
TN10-41-F	TRI@-Narrow – Narrow Contour Abutment, Straight TRI-Friction 1mm	2b
TN10-43-F	TRI@-Narrow – Narrow Contour Abutment, Straight TRI-Friction 3mm	2b
TN20-41-F	TRI@-Narrow – Contour Abutment - Angled - Friction incl. RS-TN10 - Ø 4.0mm - 1mm - 17°	2b
TN20-43-F	TRI@-Narrow – Contour Abutment - Angled - Friction incl. RS-TN10 - Ø 4.0mm - 3mm - 17°	2b
TN20-45-F	TRI@-Narrow – Angled Abutment - Standard - Friction incl. RS-TN10 - Ø 4.5mm - 20°	2b
TN30-45-F	TRI@-Narrow – Gold Castable Abutment -Friction incl. RS-TN10 - Ø 4.5mm	2b
TN40-02	TRI@-Narrow – Screw Retained Abutment - Straigh - Ø 4,5mm - 2mm	2b
TN40-04	TRI@-Narrow – Screw Retained Abutment - Straigh - Ø 4,5mm - 4mm	2b
TN60-02	TRI@-Narrow – Ball Abutment incl. CAHL - Ø 4.5mm - 2mm	2b
TN60-04	TRI@-Narrow – Ball Abutment incl. CAHL - Ø 4.5mm - 4mm	2b
TN70-07-F	TRI@-Narrow – 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	TRI@ – Healing Cap for Screw-Retained Abutment - Straight	2b
RS-TN10	TRI@-Narrow – TRI@-Narrow TRI@-Base Engaging, 4.2mmD, 0.7mm Cuff	2b
RS-TN20	TRI@-Narrow – TRI@-Narrow TRI@-Base Engaging, 4.2mmD, 0.7mm Cuff	2b
RS-TTAL	TRI@ – Replacement Retaining Screw for TTA - long	2b
TNSCS	TRI@-Narrow – Surgical Cover Screw - Ø 3.2mm	2b
TO37M08	TRI@-Octa – Implant - Ø 3.75mm - 4.8mmP - L 8mm - incl. TOSCS	2b
TO37M10	TRI@-Octa – Implant - Ø 3.75mm - 4.8mmP - L 10mm - incl. TOSCS	2b
TO37M11	TRI@-Octa – Implant - Ø 3.75mm - 4.8mmP - L 11.5mm - incl. TOSCS	2b
TO37M13	TRI@-Octa – Implant - Ø 3.75mm - 4.8mmP - L 13mm - incl. TOSCS	2b
TO41M06	TRI@-Octa – Implant - Ø 4.1mm - 4.8mmP - L 6.5mm - incl. TOSCS	2b
TO41M08	TRI@-Octa – Implant - Ø 4.1mm - 4.8mmP - L 8mm - incl. TOSCS	2b
TO41M10	TRI@-Octa – Implant - Ø 4.1mm - 4.8mmP - L 10mm - incl. TOSCS	2b
TO41M11	TRI@-Octa – Implant - Ø 4.1mm - 4.8mmP - L 11.5mm - incl. TOSCS	2b
TO41M13	TRI@-Octa – Implant - Ø 4.1mm - 4.8mmP - L 13mm - incl. TOSCS	2b
TO47M06	TRI@-Octa – Implant - Ø 4.7mm - 4.8mmP - L 6.5mm - incl. TOSCS	2b
TO47M08	TRI@-Octa – Implant - Ø 4.7mm - 4.8mmP - L 8mm - incl. TOSCS	2b

Article Nr.	Name	Class According to Annex IX of directive 93/42/EEC
TO47M10	TRI@-Octa – Implant - Ø 4.7mm - 4.8mmP - L 10mm - incl. TOSCS	2b
TO47M11	TRI@-Octa – Implant - Ø 4.7mm - 4.8mmP - L 11.5mm - incl. TOSCS	2b
TO47M13	TRI@-Octa – Implant - - Ø 4.7mm - 4.8mmP - L 13mm - incl. TOSCS	2b
TOHC51-15	TRI@-Octa – Healing Collar - Ø 5.1mm - Height 1.5mm	2b
TOHC51-30	TRI@-Octa – Healing Collar - Ø 5.1mm - Height 3mm	2b
TO10-51-ITC	TRI@ Octa 2in1 Impression Abutment - Ø 5.1mm	2b
TO10-PTA	TRI@-Octa – Temporary Abutment - Ø 5,1mm incl. RS-TO	2b
TO10-35-F	TRI@-Octa – Straight Abutment - Friction incl. RS-TO - Ø 3.5mm	2b
TO10-51-F	TRI@-Octa – Straight Abutment - Friction incl. RS-TO - Ø 5.1mm	2b
TO20-51-F	TRI@-Octa – Angled Abutment - Standard - Friction incl. RS-TO - Ø 5.1mm - 20°	2b
TO40-16	TRI@-Octa – Screw Retained Abutment - Straigth - Ø 4.5mm - 1.6mm	2b
TO40-30	TRI@-Octa – Screw Retained Abutment - Straigth - Ø 4.5mm - 3mm	2b
TO60-16	TRI@-Octa – Ball Abutment incl. CAHL - Ø 4.5mm - 1.6mm	2b
TO60-30	TRI@-Octa – 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	TRI@-Octa – Scan Abutment	2b
RS-TO	TRI@-Octa – Replacement Retaining Screw	2b
TOSCS	TRI@-Octa – Surgical Cover Screw	2b
DTC-SRA	TRI@ – Direct Transfer Component for TV40 incl. DTRS-SRA	2a
DTRS-SRA	TRI@ – Direct Transfer Retaining Screw	2a
RS-PCC	TRI@ – Replacement Retaining Screw for PCC	2b
RS-TTA	TRI@ – Replacement Retaining Screw for TTA	2b
TTA	TRI@ – Titanium Temporary Abutment incl. RS-TTA	2b
TV40-Scan	TRI@-Vent – Multi Unit Scan Body	2b
TV05-35	TRI@-Vent – Direct Transfer Component incl. DTRS - Ø 3.5mm	2a
TV05-50	TRI@-Vent – Direct Transfer Component incl. DTRS - Ø 5mm	2a
DTRS-TV05	TRI@-Vent – Direct Transfer Retaining Screw	2a
TN05-35	TRI@-Narrow – Direct Transfer Component incl. DTRS-TN05 Ø 3.5mm - blue	2a
DTRS-TN05	TRI@-Narrow – Direct Transfer Retaining Screw for TN05 – blue	2a
TO05-51	TRI@-Octa – Direct Transfer Component incl. DTRS-TO05 - Ø 5.1mm	2a
DTRS-TO05	TRI@-Octa – Replacement Screw for TO05-51	2a

EC Declaration of Conformity
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_01.

Sandro Venanzoni

Hünenberg, 2019-12-03



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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Sandro Venanzoni
Hünenberg, 2019-12-03



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	TRI® – 3,75 Dense Bone Drill - Long - Ø 2,9 - Ø 3,6mm	2a
DBD-3.7M	TRI® – 3,75 Dense Bone Drill - Medium - Ø 2,9 - Ø 3,6mm	2a
DBD-4.1L	TRI® – 4,1 Dense Bone Drill - Long - Ø 3,2 - Ø 3,9mm	2a
DBD-4.1M	TRI® – 4,1 Dense Bone Drill - Medium - Ø 3,2 - Ø 3,9mm	2a
DBD-4.7L	TRI® – 4,7 Dense Bone Drill - Long - Ø 3,8 - Ø 4,5mm	2a
DBD-4.7M	TRI® – 4,7 Dense Bone Drill - Medium - Ø 3,8 - Ø 4,5mm	2a
LD	TRI® – 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	TRI® – 3,75 Soft Bone Drill - Long - Ø 2,7 - Ø 3,1mm	2a
SBD-3.7M	TRI® – 3,75 Soft Bone Drill - Medium - Ø 2,7 - Ø 3,1mm	2a
SBD-3.7S	TRI® – 3,75 Soft Bone Drill - Short - Ø 2,7 - Ø 3,1mm	2a
SBD-4.1L	TRI® – 4,1 Soft Bone Drill - Long - Ø 3 - Ø 3,4mm	2a
SBD-4.1M	TRI® – 4,1 Soft Bone Drill - Medium - Ø 3 - Ø 3,4mm	2a
SBD-4.1S	TRI® – 4,1 Soft Bone Drill - Short - Ø 3 - Ø 3,4mm	2a
SBD-4.7L	TRI® – 4,7 Soft Bone Drill - Long - Ø 3,6 - Ø 4,0mm	2a
SBD-4.7M	TRI® – 4,7 Soft Bone Drill - Medium - Ø 3,6 - Ø 4,0mm	2a
SBD-4.7S	TRI® – 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® – TAP Drill - Ø 3,75mm	2a
TAP4.1	TRI® – TAP Drill - Ø 4,1mm	2a
TAP4.7	TRI® – 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	TRI® – Pilot Drill - Ø 2.3 - long	2a
TPD-2.3M	TRI® – Pilot Drill - Ø 2.3 - Medium	2a
TPD-2.3S	TRI® – Pilot Drill - Ø 2.3 - short	2a
VD-L	TRI® Vent – Implant Driver Long	2a
VD-S	TRI® Vent – Implant Driver Short	2a