

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_List_of_Standards_TRI_Dental_Implant_System_03.

Sandro Venanzoni
Hünenberg, 2021-05-25



Sandro Venanzoni - CTO

EC Declaration of Conformity Annex 1: Product List

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
TRI® Dental Implants - TRI®-Vent		
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, L6.5mm	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
TRI® Dental Implants - TRI®-Narrow		
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
TRI® Dental Implants - TRI®-Octa		
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
TRI® Dental Implants – TRI®-matrix®		
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
TRI® Dental Abutment - TRI®-Vent		
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
TV05-35	Direct Transfer Component incl. DTRS - Ø 3.5mm	2a
TV05-50	Direct Transfer Component incl. DTRS - Ø 5mm	2a





Article No.	Name	Class According to Annex IX of directive 93/42/EEC
DTRS-TV05	Direct Transfer Retaining Screw	2a
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
RS-MUA-D-4	Replacement Retaining Screw for MUA - 4	2b
TRI® Dental Abutment - TRI®-Narrow		
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
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
TN05-35	Direct Transfer Component incl. DTRS-TN05 Ø 3.5mm - blue	2a
DTRS-TN05	Direct Transfer Retaining Screw for TN05 - blue	2a
HC-SRAS-H	Healing Cap for Screw-Retained Abutment-High - Straight	2b
TRI® Dental Abutment - TRI®-Octa		
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
TO05-51	TO Direct Transfer Component incl. DTRS-TO05 - Ø 5.1mm	2a
DTRS-TO05	TO Replacement Screw for TO05-51	2a
TRI® Dental Abutment - TRI®-matrix®		
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-IMPR-L-37-P37	Matrix-Direct Transfer-L incl.RS-IMPR-L,RS-TV10-Ø3.7mm-P37	2a
M-IMPR-L-50-P45	Matrix-Direct Transfer-L incl.RS-IMPR-L,RS-TV10-Ø 5mm-P45	2a
M-IMPR-S-37-P37	Matrix-Direct Transfer-S incl.RS-IMPR-S,RS-TV10-Ø 4.5mm-P37	2a
M-IMPR-S-50-P45	Matrix-Direct Transfer-S incl.RS-IMPR-S,RS-TV10-Ø 5mm-P45	2a
M-RS-IMPR-L	Matrix-Direct Transfer Retaining Screw Long	2a
M-RS-IMPR-S	Matrix-Direct Transfer Retaining Screw Short	2a
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
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

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Dokumentverlauf

 GESENDET	25 / 05 / 2021 16:03:17 UTC+2	Von veronique.arnegger@tri-implants.swiss zur Signatur an Sandro Venanzoni (sv@tri.swiss) versandt IP: 88.130.76.45
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 UNTERZEICHNET	25 / 05 / 2021 16:15:46 UTC+2	Von Sandro Venanzoni (sv@tri.swiss) unterzeichnet IP: 84.227.184.35
 ABGESCHLOSSEN	25 / 05 / 2021 16:15:46 UTC+2	Das Dokument wurde abgeschlossen.

EC Declaration of Conformity
EC Directive 93/42/EEC Annex VII
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 VII.

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

REC_List_of_Standards_TRI_Dental_Implant_System_03.

Sandro Venanzoni

Hünenberg, 2021-05-25







Sandro Venanzoni - CTO

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
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
MD-L-TW	Matrix® Implant Driver Long-TW	1
MD-S-TW	Matrix® Implant Driver Short-TW	1

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STATUS	● Abgeschlossen

Dokumentverlauf

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 UNTERZEICHNET	25 / 05 / 2021 16:16:03 UTC+2	Von Sandro Venanzoni (sv@tri.swiss) unterzeichnet IP: 84.227.184.35
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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_List_of_Standards_TRI_Dental_Implant_System_03.

Sandro Venanzoni
Hünenberg, 2021-05-25







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

TITEL	EC Declaration of conformity instruments class 2a_DQS_08
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Dokumentverlauf

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