

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_12.

Sandro Venanzoni
Hünenberg, 2024-05-02



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® Prosthetic Driver ISO - Long	2a
PD-ISO-S	TRI® ISO Prosthetic Driver - Short	2a
PD-ISO-L-Ang	TRI® Prosthetic Driver ISO Angled-Long	2a
DBD-3.7L	3.7 Dense Bone Drill - Long, Ø 2.9 - Ø 3.6 mm	2a
DBD-3.7M	TV 3,75 Dense Bone Drill - Medium - Ø 2,9 - Ø 3,6mm	2a
DBD-4.1L	4.1 Dense Bone Drill - Long, Ø 3.2 - Ø 3.9 mm	2a
DBD-4.1M	TV 4,1 Dense Bone Drill - Medium - Ø 3,2 - Ø 3,9mm	2a
DBD-4.7L	4.7 Dense Bone Drill - Long, Ø 3.8 - Ø 4.5 mm	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	3.7 Soft Bone Drill - Long - Ø 2.7 - Ø 3.1 mm	2a
SBD-3.7M	TV 3,75 Soft Bone Drill - Medium - Ø 2,7 - Ø 3,1mm	2a
SBD-3.7S	3.7 Soft Bone Drill - Short - Ø 2.7 - Ø 3.1 mm	2a
SBD-4.1L	4.1 Soft Bone Drill - Long - Ø 3.0 - Ø 3.4 mm	2a
SBD-4.1M	TV 4,1 Soft Bone Drill - Medium - Ø 3 - Ø 3,4mm	2a
SBD-4.1S	4.1 Soft Bone Drill - Short - Ø 3.0 - Ø 3.4 mm	2a
SBD-4.7L	4.7 Soft Bone Drill - Long - Ø 3.6 - Ø 4.0 mm	2a
SBD-4.7M	TV 4,7 Soft Bone Drill - Medium - Ø 3,6 - Ø 4,0mm	2a
SBD-4.7S	4.7 Soft Bone Drill - Short - Ø 3.6 - Ø 4.0 mm	2a
TAP3.3	TRI®-Narrow Tap Drill - Ø 3.3 mm	2a
TAP3.7	TRI®-Vent Tap Drill - Ø 3.75 mm	2a
TAP4.1	TRI®-Vent Tap Drill - Ø 4.1 mm	2a
TAP4.7	TRI®-Vent Tap Drill - Ø 4.7 mm	2a
TND-3.3L	TN Final Drill - Long - Ø 2.4 - Ø 2.8 mm	2a
TND-3.3M	TRI-Narrow Final Drill - Medium - Ø 2.4 - Ø 2.8mm	2a
TPD-2.3L	Pilot Drill - Ø 2.3 mm - Long	2a
TPD-2.3M	Pilot Drill - Ø 2.3 - Medium	2a
TPD-2.3S	Pilot Drill - Ø 2.3 mm - 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	Round Bur	2a

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