



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 12 1064 QS/NB/a

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the products – medical devices of Class IIb:

TRI Dental Implant System

(For detailed specification refer to the annex; pages 1-8)
manufactured by company

TRI Dental Implants Int. AG

Lindenstrasse 14 - CH 6340 Baar, Switzerland

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report Nos. 803601719/2012 and 343602424/2014, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 20th December 2017 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023



R. Radomir Čevelík

RNDr. Radomír Čevelík

Issued in Zlín, on 31st January 2014

Replaces the withdrawn EC Certificate No. 12.1064 QS/NB issued on 21st December 2012

Representative of the Notified Body No. 1023



Annex to EC CERTIFICATE

No. 12 1064 QS/NB/a

Issued for the company:

TRI Dental Implants Int. AG

Lindenstrasse 14 - CH 6340 Baar, Switzerland

List of the medical devices covered by the Certificate:

Article Nr.	Name	Class	Rule
08505	Locator Impression Coping	IIb	8
08519	Male Processing Package	IIb	8
08524	Replacement Male - clear	IIb	8
08527	Replacement Male - pink	IIb	8
08529	Replacement Male - blue	IIb	8
08530	Locator Female Analog	IIb	8
08547	Extended Range Replacement Male - green	IIb	8
08548	Extended Range Replacement Male - red	IIb	8
08626	Locator Abutment 6mm	IIb	8
08661	Locator Abutment 0mm	IIb	8
08662	Locator Abutment 1mm	IIb	8
08663	Locator Abutment 2mm	IIb	8
08664	Locator Abutment 3mm	IIb	8
08665	Locator Abutment 4mm	IIb	8
CAHL	Cap Attachment Housing and Liner	IIb	8
CALB	Cap Attachment Liner - Lab	IIb	8
CALG	Cap Attachment Liner - Rigid retention	IIb	8
CALT	Cap Attachment Liner - Standard	IIb	8
DTC-SRA	Direct Transfer Component for TV40 incl. DTRS-SRA	IIb	8
DTRS-SRA	Direct Transfer Retaining Screw	IIb	8
DTRS-TN05	Direct Transfer Retaining Screw for TN05 - blue	IIb	8
DTRS-TO05	TO Replacement Screw for TO05-51	IIb	8
DTRS-TV05	Direct Transfer Retaining Screw	IIb	8
HC-SRAS	Healing Cap for Screw-Retained Abutment - Straight	IIb	8
IA-SRA	Tapered Abutment Replica	IIb	8
ITC	Indirect Transfer Cap	IIb	8

Page 1 of 8



Paul Veselý
RNDr. Radomír Čevelík

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Issued for the company:

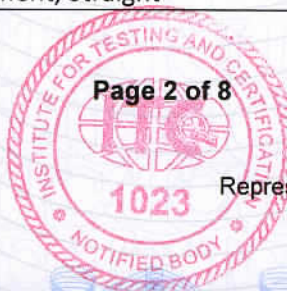
TRI Dental Implants Int. AG

Lindenstrasse 14 - CH 6340 Baar, Switzerland

List of the medical devices covered by the Certificate:

Locator height 1	Locator Abutment height 1	IIb	8
Locator height 2	Locator Abutment height 2	IIb	8
PCC	Plastic Castable Coping incl. RS-PCC	IIb	8
RS-PCC	Replacement Retaining Screw for PCC	IIb	8
RS-PCC-Lab	Replacement Retaining Screw - lab	IIb	8
RS-TN10	Replacement Retaining Screw - blue	IIb	8
RS-TN10-Lab	Replacement Retaining Screw - lab - green	IIb	8
RS-TN20	Replacement Retaining Screw for TN20 for TN20	IIb	8
RS-TN20-Lab	Replacement Retaining Screw - lab - red	IIb	8
RS-TO	TO Replacement Retaining Screw	IIb	8
RS-TO-Lab	TO Replacement Retaining Screw - Lab Use - Red	IIb	8
RS-TTA	Replacement Retaining Screw for TTA	IIb	8
RS-TTAL	Replacement Retaining Screw for TTA - long	IIb	8
RS-TV10	Replacement Retaining Screw	IIb	8
RS-TV10-Lab	Replacement Retaining Screw - lab	IIb	8
RS-TV20	Replacement Retaining Screw	IIb	8
RS-TV20-Lab	Replacement Retaining Screw - lab	IIb	8
Ti	Cap Attachment Housing	IIb	8
TN05-35	Direct Transfer Component incl. DTRS-TN05 Ø 3.5mm - blue	IIb	8
TN06-35-ITC	Indirect Transfer Abutment - blue	IIb	8
TN10-35-F	Straight Abutment - Friction incl. RS-TN10 - Ø 3,5mm	IIb	8
TN10-41-F	Contour Abutment - Straight - Friction incl. RS-TN10 - Ø 4mm - 1mm	IIb	8
TN10-43-F	Contour Abutment - Straight - Friction incl. RS-TN10 - Ø 4mm - 3mm	IIb	8
TN10-PTA	Temporary Abutment, Straight	IIb	8

Page 2 of 8



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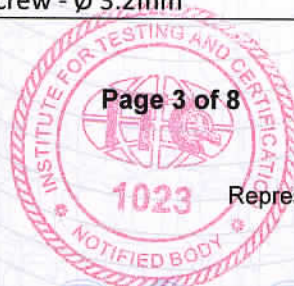
TRI Dental Implants Int. AG

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List of the medical devices covered by the Certificate:

TN20-35-F	Angled Abutment - Standard - Friction incl. RS-TN20 - \emptyset 3.5mm - 20°	IIb	8
TN20-41-F	Contour Abutment - Angled - Friction incl. RS-TN10 - \emptyset 4.0mm - 1mm - 17°	IIb	8
TN20-43-F	Contour Abutment - Angled - Friction incl. RS-TN10 - \emptyset 4.0mm - 3mm - 17°	IIb	8
TN30-45	Gold Castable Abutment incl. RS-TN10 - \emptyset 4.5mm	IIb	8
TN33B11	TRI Narrow Implant - B - SBA - \emptyset 3.3mm - 11mm	IIb	8
TN33B13	TRI Narrow Implant - B - SBA - \emptyset 3.3mm - 13mm	IIb	8
TN33B16	TRI Narrow Implant - B - SBA - \emptyset 3.3mm - 16mm	IIb	8
TN33M11	TRI Narrow Implant - M - SBA - \emptyset 3.3mm - 11mm	IIb	8
TN33M13	TRI Narrow Implant - M - SBA - \emptyset 3.3mm - 13mm	IIb	8
TN33M16	TRI Narrow Implant - M - SBA - \emptyset 3.3mm - 16mm	IIb	8
TN40-01	Screw Retained Abutment - Straight - \emptyset 4,5mm - 1mm	IIb	8
TN40-02	Screw Retained Abutment - Straight - \emptyset 4,5mm - 2mm	IIb	8
TN40-04	Screw Retained Abutment - Straight - \emptyset 4,5mm - 4mm	IIb	8
TN60-02	Ball Abutment incl. CAHL - \emptyset 4.5mm - 2mm	IIb	8
TN60-04	Ball Abutment incl. CAHL - \emptyset 4.5mm - 4mm	IIb	8
TNHC35-30	Healing Collar - \emptyset 3,5mm - 3mm - blue	IIb	8
TNHC35-45	Healing Collar - \emptyset 3,5mm - 4.5mm - blue	IIb	8
TNHC35-60	Healing Collar - \emptyset 3,5mm - 6mm - blue	IIb	8
TNHC35-60-A	Healing Collar - Aesthetic - \emptyset 3,5mm - 6mm - blue	IIb	8
TNHC45-30	Healing Collar - \emptyset 4,5mm - 3mm - blue	IIb	8
TNHC45-50	Healing Collar - \emptyset 4,5mm - 5mm - blue	IIb	8
TNIA-1	Implant Analog - blue	IIb	8
TNIA-5	Implant Analog - blue	IIb	8
TNSCS	Surgical Cover Screw - \emptyset 3.2mm	IIb	8

Page 3 of 8



R. Radomir Čevelj

RNDR. Radomir Čevelj

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TO05-51	TO Direct Transfer Component incl. DTRS-TO05 - \varnothing 5.1mm	IIb	8
TO10-35-F	TO Straight Abutment - Friction incl. RS-TO - \varnothing 3.5mm	IIb	8
TO10-35-ITC	TO Transfer and Straight Abutment incl. RS-TO and ITC - \varnothing 3.5mm	IIb	8
TO10-51-F	TO Straight Abutment - Friction incl. RS-TO - \varnothing 5.1mm	IIb	8
TO10-51-ITC	TO Transfer and Straight Abutment incl. RS-TO and ITC - \varnothing 5.1mm	IIb	8
TO10-PTA	TO Temporary Abutment - \varnothing 5,1mm incl. RS-TO	IIb	8
TO20-51-F	TO Angled Abutment - Standard - Friction incl. RS-TO - \varnothing 5.1mm - 20°	IIb	8
TO30-51-F	TO Gold Castable Abutment - Friction incl. RSTO - \varnothing 5.1mm	IIb	8
TO37M08	TO Implant - \varnothing 3.75mm - 4.8mmP - Length 8mm - incl. TOSCS	IIb	8
TO37M10	TO Implant - \varnothing 3.75mm - 4.8mmP - Length 10mm - incl. TOSCS	IIb	8
TO37M11	TO Implant - \varnothing 3.75mm - 4.8mmP - Length 11.5mm - incl. TOSCS	IIb	8
TO37M13	TO Implant - \varnothing 3.75mm - 4.8mmP - Length 13mm - incl. TOSCS	IIb	8
TO37M16	TO Implant - \varnothing 3.75mm - 4.8mmP - Length 16mm - incl. TOSCS	IIb	8
TO40-16	TO Screw Retained Abutment - Straight - \varnothing 4.5mm - 1.6mm	IIb	8
TO40-30	TO Screw Retained Abutment - Straight - \varnothing 4.5mm - 3mm	IIb	8
TO41M06	TO Implant - \varnothing 4.1mm - 4.8mmP - Length 6.5mm - incl. TOSCS	IIb	8

Page 4 of 8



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TO41M08	TO Implant - Ø 4.1mm - 4.8mmP - Length 8mm - incl. TOSCS	IIb	8
TO41M10	TO Implant - Ø 4.1mm - 4.8mmP - Length 10mm - incl. TOSCS	IIb	8
TO41M11	TO Implant - Ø 4.1mm - 4.8mmP - Length 11.5mm - incl. TOSCS	IIb	8
TO41M13	TO Implant - Ø 4.1mm - 4.8mmP - Length 13mm - incl. TOSCS	IIb	8
TO41M16	TO Implant - Ø 4.1mm - 4.8mmP - Length 16mm - incl. TOSCS	IIb	8
TO47M06	TO Implant - Ø 4.7mm - 4.8mmP - Length 6.5mm - incl. TOSCS	IIb	8
TO47M08	TO Implant - Ø 4.7mm - 4.8mmP - Length 8mm - incl. TOSCS	IIb	8
TO47M10	TO Implant - Ø 4.7mm - 4.8mmP - Length 10mm - incl. TOSCS	IIb	8
TO47M11	TO Implant - Ø 4.7mm - 4.8mmP - Length 11.5mm - incl. TOSCS	IIb	8
TO47M13	TO Implant - Ø 4.7mm - 4.8mmP - Length 13mm - incl. TOSCS	IIb	8
TO47M16	TO Implant - Ø 4.7mm - 4.8mmP - Length 16mm - incl. TOSCS	IIb	8
TO60-16	Ball Abutment incl. CAHL - Ø 4.5mm - 1.6mm	IIb	8
TO60-30	Ball Abutment incl. CAHL - Ø 4.5mm - 3mm	IIb	8
TO70-07-F	TO Titanium Bonding Base - 0.7mm Cuff	IIb	8
TO70-Scan	TO Scan Abutment	IIb	8
TOHC51-15	TO Healing Collar - Ø 5.1mm - Height 1.5mm	IIb	8
TOHC51-30	TO Healing Collar - Ø 5.1mm - Height 3mm	IIb	8

Page 5 of 8



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TOIA	TO Implant Analog	IIb	8
TOSCS	TO Surgical Cover Screw	IIb	8
TTA	Titanium Temporary Abutment incl. RS-TTA	IIb	8
TV05-35	Direct Transfer Component incl. DTRS - Ø 3.5mm	IIb	8
TV05-50	Direct Transfer Component incl. DTRS - Ø 5mm	IIb	8
TV10-35	Straight Abutment incl. RS-TV10 - Ø 3.5mm	IIb	8
TV10-35-F	Straight Abutment - Friction incl. RS-TV10 - Ø 3.5mm	IIb	8
TV10-35-ITC	Transfer and Straight Abutment incl. ITC - Ø 3.5mm	IIb	8
TV10-41-F	Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 1mm	IIb	8
TV10-43-F	Contour Abutment - Straight - Friction incl. RS-TV10 - Ø 4.5mm - 3mm	IIb	8
TV10-50	Straight Abutment incl. RS-TV10 - Ø 5mm	IIb	8
TV10-50-F	Straight Abutment - Friction incl. RS-TV10 - Ø 5mm	IIb	8
TV10-50-ITC	Transfer and Straight Abutment incl. ITC - Ø 5.0mm	IIb	8
TV10-PTA	Temporary Abutment Straight	IIb	8
TV20-41-F	Contour Abutment - Angled - Friction incl. RS-TV20 - Ø 4.5mm - 1mm - 17°	IIb	8
TV20-43-F	Contour Abutment - Angled - Friction incl. RS-TV20 - Ø 4.5mm - 3mm - 17°	IIb	8
TV20-50-F	Angled Abutment - Standard - Friction incl. RS-TV20 - Ø 5mm - 20°	IIb	8
TV30-50	Gold Castable Abutment incl. RS-TV10 - Ø 5mm	IIb	8
TV37B08	TRI Vent Implant - B - SBA - 3,5 - Ø 3.7mm - 8mm	IIb	8
TV37B10	TRI Vent Implant - B - SBA - 3,5 - Ø 3.7mm - 10mm	IIb	8
TV37B11	TRI Vent Implant - B - SBA - 3,5 - Ø 3.7mm - 11mm	IIb	8
TV37B13	TRI Vent Implant - B - SBA - 3,5 - Ø 3.7mm - 13mm	IIb	8
TV37B16	TRI Vent Implant - B - SBA - 3,5 - Ø 3.7mm - 16mm	IIb	8

Page 6 of 8



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List of the medical devices covered by the Certificate:

TV37M08	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 8mm	IIb	8
TV37M10	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 10mm	IIb	8
TV37M11	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 11mm	IIb	8
TV37M13	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 13mm	IIb	8
TV37M16	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 16mm	IIb	8
TV40-01	Screw Retained Abutment - Straight - Ø 4.5mm - 1mm	IIb	8
TV40-02	Screw Retained Abutment - Straight - Ø 4.5mm - 2mm	IIb	8
TV40-04	Screw Retained Abutment - Straight - Ø 4.5mm - 4mm	IIb	8
TV40-06	Screw Retained Abutment - Straight - Ø 4.5mm - 6mm	IIb	8
TV41B06	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 6mm	IIb	8
TV41B08	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 8mm	IIb	8
TV41B10	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 10mm	IIb	8
TV41B11	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 11mm	IIb	8
TV41B13	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 13mm	IIb	8
TV41B16	TRI Vent Implant - B - SBA - 3,5 - Ø 4.1mm - 16mm	IIb	8
TV41M06	TRI Vent Implant - M - SBA - 3,5 - Ø 3.7mm - 6mm	IIb	8
TV41M08	TRI Vent Implant - M - SBA - 3,5 - Ø 4.1mm - 8mm	IIb	8
TV41M10	TRI Vent Implant - M - SBA - 3,5 - Ø 4.1mm - 10mm	IIb	8
TV41M11	TRI Vent Implant - M - SBA - 3,5 - Ø 4.1mm - 11mm	IIb	8
TV41M13	TRI Vent Implant - M - SBA - 3,5 - Ø 4.1mm - 13mm	IIb	8
TV41M16	TRI Vent Implant - M - SBA - 3,5 - Ø 4.1mm - 16mm	IIb	8
TV47B06	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 6mm	IIb	8
TV47B08	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 8mm	IIb	8
TV47B10	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 10mm	IIb	8
TV47B11	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 11mm	IIb	8
TV47B13	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 13mm	IIb	8
TV47B16	TRI Vent Implant - B - SBA - 3,5 - Ø 4.7mm - 16mm	IIb	8
TV47M06	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 6mm	IIb	8

Page 7 of 8



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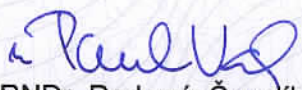
TRI Dental Implants Int. AG

Lindenstrasse 14 - CH 6340 Baar, Switzerland

List of the medical devices covered by the Certificate:

TV47M08	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 8mm	IIb	8
TV47M10	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 10mm	IIb	8
TV47M11	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 11mm	IIb	8
TV47M13	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 13mm	IIb	8
TV47M16	TRI Vent Implant - M - SBA - 3,5 - Ø 4.7mm - 16mm	IIb	8
TV50-34-F	Screw Retained Abutment - Angulated 30° - Ø 4.5mm - 4mm	IIb	8
TV60-02	Ball Abutment incl. CAHL - Ø 4.5mm - 2mm	IIb	8
TV60-04	Ball Abutment incl. CAHL - Ø 4.5mm - 4mm	IIb	8
TV70-07-F	Titanium Bonding Base, 4,5mmD, 0,7mm Cuff	IIb	8
TV70-20-F	Titanium Bonding Base, 4,5mmD, 2,0mm Cuff	IIb	8
TVHC35-30	Healing Collar - Ø 3.5mm - 3mm	IIb	8
TVHC35-45	Healing Collar - Ø 3.5mm - 4.5mm	IIb	8
TVHC35-60	Healing Collar - Ø 3.5mm - 6mm	IIb	8
TVHC35-60-A	Healing Collar - Aesthetic - Ø 3.5mm - 6mm	IIb	8
TVHC50-30	Healing Collar - Ø 5mm - 3mm	IIb	8
TVHC50-45	Healing Collar - Ø 5mm - 4.5mm	IIb	8
TVHC50-60	Healing Collar - Ø 5mm - 6mm	IIb	8
TVHC50-60-A	Healing Collar - Aesthetic - Ø 5mm - 6mm	IIb	8
TVIA-1	Implant Analog	IIb	8
TVIA-5	Implant Analog	IIb	8
TVSCS	Surgical Cover Screw - Ø 3.5mm	IIb	8
TVSCS-SL	Surgical Cover Screw for Sinus Lift - Ø 5.2mm	IIb	8




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