

**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\_Regulatory List\_TRI Dental Implant System\_11.

Sandro Venanzoni  
Hünenberg, 2024-05-02



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Sandro Venanzoni - CTO

## EC Declaration of Conformity Annex 1: Product List

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
<b>TRI® Dental Implants - TRI®-Vent</b>		
TV37M08	TRI®-Vent Implant Ø 3.75 mm - L 8 mm	2b
TV37M10	TRI®-Vent Implant Ø 3.75 mm - L 10 mm	2b
TV37M11	TRI®-Vent Implant Ø 3.75 mm - L 11.5 mm	2b
TV37M13	TRI®-Vent Implant Ø 3.75 mm - L 13 mm	2b
TV37M16	TRI®-Vent Implant Ø 3.75 mm - L 16 mm	2b
TV41M06	TRI®-Vent Implant Ø 4.1 mm - L 6.5 mm	2b
TV41M08	TRI®-Vent Implant Ø 4.1 mm - L 8 mm	2b
TV41M10	TRI®-Vent Implant Ø 4.1 mm - L 10 mm	2b
TV41M11	TRI®-Vent Implant Ø 4.1 mm - L 11.5 mm	2b
TV41M13	TRI®-Vent Implant Ø 4.1 mm - L 13 mm	2b
TV41M16	TRI®-Vent Implant Ø 4.1 mm - L 16 mm	2b
TV47M06	TRI®-Vent Implant Ø 4.7 mm - L 6.5 mm	2b
TV47M08	TRI®-Vent Implant Ø 4.7 mm - L 8 mm	2b
TV47M10	TRI®-Vent Implant Ø 4.7 mm - L 10 mm	2b
TV47M11	TRI®-Vent Implant Ø 4.7 mm - L 11.5 mm	2b
TV47M13	TRI®-Vent Implant Ø 4.7 mm - L 13 mm	2b
TV47M16	TRI®-Vent Implant Ø 4.7 mm - L 16 mm	2b
<b>TRI® Dental Implants - TRI®-Narrow</b>		
TN33M10	TRI®-Narrow Implant Ø 3.3 mm - L 10 mm	2b
TN33M11	TRI®-Narrow Implant Ø 3.3 mm - L 11 mm	2b
TN33M13	TRI®-Narrow Implant Ø 3.3 mm - L 13 mm	2b
TN33M16	TRI®-Narrow Implant Ø 3.3 mm - L 16 mm	2b
<b>TRI® Dental Implants - TRI®-Octa</b>		
TO37M08	TRI®-Octa Implant - Ø 3.75mm - L 8mm	2b
TO37M10	TRI®-Octa Implant - Ø 3.75mm - L 10mm	2b
TO37M11	TRI®-Octa Implant - Ø 3.75mm - L 11.5mm	2b
TO37M13	TRI®-Octa Implant - Ø 3.75mm - L 13mm	2b
TO41M06	TRI®-Octa Implant - Ø 4.1mm - L 6.5mm	2b
TO41M08	TRI®-Octa Implant - Ø 4.1mm - L 8mm	2b
TO41M10	TRI®-Octa Implant - Ø 4.1mm - L 10mm	2b
TO41M11	TRI®-Octa Implant - Ø 4.1mm - L 11.5mm	2b
TO41M13	TRI®-Octa Implant - Ø 4.1mm - L 13mm	2b
TO47M06	TRI®-Octa Implant - Ø 4.7mm - L 6.5mm	2b

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
TO47M08	TRI®-Octa Implant - Ø 4.7mm - L 8mm	2b
TO47M10	TRI®-Octa Implant - Ø 4.7mm - L 10mm	2b
TO47M11	TRI®-Octa Implant - Ø 4.7mm - L 11.5mm	2b
TO47M13	TRI®-Octa Implant - Ø 4.7mm - L 13mm	2b
<b>TRI® Dental Implants – TRI®-matrix®</b>		
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

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
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 - L11.5mm-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
<b>TRI® Dental Abutment - TRI®-Vent</b>		
TVHC35-30	TV Healing Collar - Ø 3.5 mm - H 3 mm	2b
TVHC35-45	TV Healing Collar - Ø 3.5 mm - H 4.5 mm	2b
TVHC35-60	TV Healing Collar - Ø 3.5 mm - H 6 mm	2b
TVHC35-60-A	Healing Collar - Aesthetic - Ø 3.5mm - 6mm	2b
TVHC50-30	TV Healing Collar - Ø 5 mm - H 3 mm	2b
TVHC50-45	TV Healing Collar - Ø 5 mm - H 4.5 mm	2b
TVHC50-60	TV Healing Collar - Ø 5 mm - H 6 mm	2b
TVHC50-60-A	Healing Collar - Aesthetic - Ø 5mm - 6mm	2b
TV10-35-ITC	TV 2in1 Impression Abutment - Ø 3.5 mm	2b

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
TV10-50-ITC	TV 2in1 Impression Abutment - Ø 5 mm	2b
TV10-EHA-50	TV Esthetic Healing Abutment - Ø 5 mm	2b
TV10-EHA-70	TV Esthetic Healing Abutment - Ø 7 mm	2b
TV10-PTA	TV Temporary Abutment, Straight - Ø 4.5 mm	2b
TV10-TTA	Temporary Abutment Straight, Ø 4.5mm	2b
TV10-35-F	TV Straight Abutment, TRI®-Friction - Ø 3.5 mm	2b
TV10-41-F	TV Contour Abutment, Straight, TRI®-Friction, 1 mm	2b
TV10-43-F	TV Contour Abutment, Straight, TRI®-Friction, 3 mm	2b
TV10-50-F	TV Straight Abutment, TRI®-Friction - Ø 5 mm	2b
TV20-41-F	TV Contour Abutment, Angled, TRI®-Frict., 17°, 1mm	2b
TV20-43-F	TV Contour Abutment, Angled, TRI®-Frict. 17°, 3mm	2b
TV20-50-F	TV Angled Abutment, Standard, TRI®-Frict. - 20°	2b
TV30-50-F	TV Gold Castable Abutment, TRI®-Friction - Ø 5 mm	2b
TV35-50	TV NEM Castable Abutment - Ø 5 mm	2b
TV40-01	TV Screw Retained Abut., Straight - Ø 4.5mm, H 1mm	2b
TV40-02	TV Screw Retained Abut., Straight - Ø 4.5mm, H 2mm	2b
TV40-04	TV Screw Retained Abut., Straight - Ø 4.5mm, H 4mm	2b
TV40-06	TV Screw Retained Abut., Straight - Ø 4.5mm, H 6mm	2b
TV50-17	TV Screw Retained Abut.,Angled 17°, Ø 4.5mm, H 2mm	2b
TV50-30	TV Screw Retained Abut.,Angled 30°, Ø 4.5mm, H 3mm	2b
TV50-30-S	TV Screw Retained Abut., Angled 30°, Ø 4.5mm-Short	2b
TV60-02	TV Ball Abutment incl. CAHL - Ø 4.5 mm - H 2 mm	2b
TV60-04	TV Ball Abutment incl. CAHL - Ø 4.5 mm - H 4 mm	2b
TV70-07-F	TV TRI®-Base Engaging - Ø 4.5 mm, 0.7 mm Cuff	2b
TV70-07-NE	TV TRI®-Base Non-Engaging - Ø 4.5 mm, 0.7 mm Cuff	2b
TV70-20-F	TV TRI®-Base Engaging - Ø 4.5 mm, 2.0 mm Cuff	2b
TV70-20-NE	TV TRI®-Base Non-Engaging - Ø 4.5 mm, 2.0 mm Cuff	2b
TV70-Blank-F	TV Milling Blank - Ø 11.5 mm, 0.7 mm Cuff	2b
TV70-SCAN	TV Scanbody	2b
RS-TV10	TV Replacement Retaining Screw	2b
TVSCS	TV Surgical Cover Screw - Ø 3.5 mm	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	TV Replacement Retaining Screw	2b
TV40-Scan	Multi-Unit Scanbody	2b

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
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
<b>TRI® Dental Abutment - TRI®-Narrow</b>		
TNHC35-30	TN Healing Collar - Ø 3.5 mm - H 3 mm - blue	2b
TNHC35-45	TN Healing Collar - Ø 3.5 mm - H 4.5 mm - blue	2b
TNHC35-60	TN Healing Collar - Ø 3.5 mm - H 6mm - blue	2b
TNHC35-60-A	Healing Collar - Aesthetic - Ø 3,5mm - 6mm - blue	2b
TNHC45-30	TN Healing Collar - Ø 4.5 mm - H 3 mm - blue	2b
TNHC45-50	TN Healing Collar - Ø 4.5 mm - H 5 mm - blue	2b
TN10-PTA	TN Temporary Abutment, Straight - Ø 3.5 mm	2b
TN10-35-F	TN Straight Abutment, TRI®-Friction - Ø 3.5 mm	2b
TN10-41-F	TN Contour Abutment, Straight, TRI®-Friction, 1 mm	2b
TN10-43-F	TN Contour Abutment, Straight, TRI®-Friction, 3 mm	2b
TN20-41-F	TN Contour Abutment, Angled, TRI®-Frict., 17°, 1mm	2b
TN20-43-F	TN Contour Abutment, Angled, TRI®-Frict., 17°, 3mm	2b
TN20-45-F	TN Angled Abutment, Standard, TRI®-Frict. - 20°	2b
TN30-45-F	TN Gold Castable Abutment, TRI®-Friction - Ø 4.5mm	2b
TN40-02	TN Screw Retained Abut., Straight - Ø 4.5mm, H 2mm	2b
TN40-04	TN Screw Retained Abut., Straight - Ø 4.5mm, H 4mm	2b
TN60-02	TN Ball Abutment incl. CAHL - Ø 4.5 mm - H 2 mm	2b
TN60-04	TN Ball Abutment incl. CAHL - Ø 4.5 mm - H 4 mm	2b
TN70-07-F	TN TRI®-Base Engaging - Ø 4.2 mm, 0.7 mm Cuff	2b
TN70-07-NE	TN TRI®-Base Non-Engaging - Ø 4.2 mm, 0.7 mm Cuff	2b
TN70-Blank-F	TN Milling Blank - Ø 11.5 mm, 0.7 mm Cuff	2b
TN70-Scan	TN Scanbody	2b
HC-SRAS	Healing Cap for Screw-Retained Abutment-Straight	2b
RS-TN10	TN Replacement Retaining Screw	2b
RS-TN20	TN Replacement Retaining Screw	2b
RS-TTAL	Replacement Retaining Screw for TTA - Long	2b
TNSCS	TN Surgical Cover Screw - Ø 3.2 mm	2b
HC-SRAS-H	Healing Cap for Screw-Retained Abut.High-Straight	2b

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
<b>TRI® Dental Abutment - TRI®-Octa</b>		
TOHC51-15	TO Healing Collar - Ø 5.1 mm - H 1.5 mm - pink	2b
TOHC51-30	TO Healing Collar - Ø 5.1 mm - H 3 mm - pink	2b
TO10-51-ITC	TO 2in1 Impression Abutment - Ø 5.1 mm	2b
TO10-PTA	TO Temporary Abutment, Straight - Ø 5.1 mm	2b
TO10-35-F	TO Straight Abutment, TRI®-Friction - Ø 3.5 mm	2b
TO10-51-F	TO Straight Abutment, TRI®-Friction - Ø 5.1 mm	2b
TO20-51-F	TO Angled Abutment, Standard - 20°, TRI-Friction	2b
TO40-16	TO Screw Retained Abut., Straight - Ø 4.5mm, H1.6mm	2b
TO40-30	TO Screw Retained Abut., Straight - Ø 4.5mm, H 3mm	2b
TO60-16	TO Ball Abutment incl. CAHL - Ø 4.5 mm - 1.6 mm	2b
TO60-30	TO Ball Abutment incl. CAHL - Ø 4.5 mm - 3 mm	2b
TO70-07-F	TO TRI®-Base Engaging - Ø 5.1 mm, 0.7 mm Cuff	2b
TO70-07-NE	TO TRI®-Base Non-Engaging - Ø 5.1 mm, 0.7 mm Cuff	2b
TO70-Blank-F	TO Milling Blank - Ø 11.5 mm, 0.7 mm Cuff	2b
TO70-Scan	TO Scanbody	2b
RS-TO	TO Replacement Retaining Screw	2b
TOSCS	TO Surgical Cover Screw - Ø 3.5 mm	2b
<b>TRI® Dental Abutment - TRI®-matrix®</b>		
M-HC-37-15-P37	Matrix®-Healing Collar - Ø 3.7 mm - 1.5 mm - P37	2b
M-HC-37-30-P37	Matrix®-Healing Collar - Ø 3.7 mm - 3 mm - P37	2b
M-HC-37-45-P37	Matrix®-Healing Collar - Ø 3.7 mm - 4.5 mm - P37	2b
M-HC-37-60-P37	Matrix®-Healing Collar - Ø 3.7 mm - 6 mm - P37	2b
M-HC-50-30-P37	Matrix®-Healing Collar - Ø 5 mm - 3 mm - P37	2b
M-HC-50-45-P37	Matrix®-Healing Collar - Ø 5 mm - 4.5 mm - P37	2b
M-HC-50-60-P37	Matrix®-Healing Collar - Ø 5 mm - 6 mm - P37	2b
M-HC-45-15-P45	Matrix®-Healing Collar - Ø 4.5 mm - 1.5 mm - P45	2b
M-HC-45-30-P45	Matrix®-Healing Collar - Ø 4.5 mm - 3 mm - P45	2b
M-HC-45-45-P45	Matrix®-Healing Collar - Ø 4.5 mm - 4.5 mm - P45	2b
M-HC-45-60-P45	Matrix®-Healing Collar - Ø 4.5 mm - 6 mm - P45	2b
BLM-Prov-EN-P37	BLM-Temporary Abutment, Straight, Ø 4.9mm-EN-P37	2b
BLM-Prov-NE-P37	BLM-Temporary Abutment, Straight, Ø 4.9mm-NE-P37	2b

Article No.	Name	Class According to Annex IX of directive 93/42/EEC
BLM-Prov-EN-P45	BLM-Temporary Abutment, Straight, Ø 4.9mm-EN-P45	2b
BLM-Prov-NE-P45	BLM-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	TLM-Temporary Abutment, Straight, Ø 4.9mm-EN-P37	2b
TLM-Prov-NE-P37	TLM-Temporary Abutment, Straight, Ø 4.9mm-NE-P37	2b
TLM-Prov-EN-P45	TLM-Temporary Abutment, Straight, Ø 4.9mm-EN-P45	2b
TLM-Prov-NE-P45	TLM-Temporary Abutment, Straight, Ø 4.9mm-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, Ø4.5mm, 0.7mm Cuff-EN-P37	2b
M-70-07-NE-P37	Matrix®-Base Non-Engag., Ø4.5mm, 0.7mm Cuff-NE-P37	2b
M-70-07-EN-P45	Matrix®-Base Engaging, Ø4.8mm, 0.7mm Cuff-EN-P45	2b
M-70-07-NE-P45	Matrix®-Base Non-Engag., Ø4.8mm, 0.7mm Cuff-NE-P45	2b
M-CS-P37	Matrix®-Surgical Cover Screw - Ø 3.7 mm - P37	2b
M-CS-P45	Matrix®-Surgical Cover Screw - Ø 4.5 mm - 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	Matrix® Clinical Screw 2.25mm	2b
M-SCRW-2.6	Replacement Retaining Screw	2b
M-SCRW-2.8	Matrix® Clinical Screw 2.8mm	2b
M-SCRW-2.8-L	Matrix® Clinical Screw Long 2.8mm	2b
M-SCRW-3.25	Matrix® Clinical Screw 3.25mm	2b
M-MUA-P37	Matrix® Multiunit Abutment P37	2b
M-MUA-P45	Matrix® Multiunit Abutment P45	2b



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