



EC Declaration of Conformity

Manufacturers Name: TOR VM Ltd.

Manufacturers Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421, Russia
Manufacturing site: Kulibina, 15c, Voronezh, 394029, Russia
Telephone: +7 495 2255417

SRN (Single Registration Number): RU-MF-000016957

Authorized Representative Name (if applicable): Mr. Gregor Kostunov

Authorized Representative Address (if applicable): Untere Seegasse 54, DE-69124, Heidelberg, Germany
Telephone:+49 (17) 626 400 019

SRN (Single Registration Number): DE-AR-000006585

Basic UDI-DI: 463003499METMATBB / 463003499PLCMATB8

Name of the Device (s): **Dental Matrix Bands.** Metal Matrices / Transparent Matrices
(Annex specifying List of Products is an integral part of this Declaration)

Product code: GMDN 38786, Dental Matrix Band, Single-Use

Classification: Class I

Notified Body name: for Class I not relevant.

Conformity assessment route: Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV, Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745;
EN 1041:2008, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2021

This declaration of conformity is issued under the sole responsibility of TOR VM. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Date of the first CE mark: 10.08.2005

Signature:

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Dr. Oleg Mikhalev
General manager



Place and date (dd.mm.yyyy) of issue:

Moscow, Russia
10.01.2022



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List of Products

Catalogue number	Product name
Metal Matrices	
1.0930	Metal Matrix Bands for Premolars
1.0932	Metal Matrix Bands for Premolars
1.0933	Metal Matrix Bands for Premolars
1.0935	Metal Matrix Bands for Premolars
1.0929	Metal Sub-Gingival Matrix Bands
1.0931	Metal Matrix Bands for Molars
1.1932	Metal Matrix Bands for Molars
1.1933	Metal Matrix Bands for Molars
1.1935	Metal Matrix Bands for Molars
1.1937	Metal Matrix Bands for Molars
1.936L	Metal Matrix Bands for Anteriors
1.1938	U-Shaped Metal Matrix Bands
1.1939	U-Shaped Metal Matrix Bands
1.1940	U-Shaped Metal Matrix Bands
1.380	Metal Matrix Bands
1.381	Metal Matrix Bands
1.382	Metal Strips
1.382(7)	Metal Strips
1.383	Metal Strips
1.390	Metal Striproll
1.390(5)	Metal Striproll
1.391	Metal Striproll
1.392	Metal Striproll
1.392(5)	Metal Striproll
1.393	Metal Striproll
1.595	Loop Matrices
1.597	Loop Matrices
1.501	Metal Contoured Matrices for Premolars
1.502	Metal Contoured Matrices for Premolars
1.503	Metal Contoured Matrices for Premolars
1.504	Metal Contoured Matrices for Premolars
1.505	Metal Contoured Matrices for Premolars
1.506	Metal Contoured Matrices for Premolars
1.507	Metal Contoured Matrices for Premolars
1.511	Metal Contoured Matrices for Molars
1.512	Metal Contoured Matrices for Molars
1.513	Metal Contoured Matrices for Molars
1.514	Metal Contoured Matrices for Molars
1.515	Metal Contoured Matrices for Molars
1.516	Metal Contoured Matrices for Molars
1.517	Metal Contoured Matrices for Molars
1.500	Metal Contoured Matrices for Premolars
1.500+	Metal Contoured Matrices for Premolars
1.510	Metal Contoured Matrices for Molars
1.510+	Metal Contoured Matrices for Molars
1.541	Metal Contoured Matrices for Premolars Combined with Clamp
1.542	Metal Contoured Matrices for Premolars Combined with Clamp
1.543	Metal Contoured Matrices for Premolars Combined with Clamp
1.544	Metal Contoured Matrices for Premolars Combined with Clamp
1.545	Metal Contoured Matrices for Premolars Combined with Clamp



List of Products. Continued

Catalogue number	Product name
1.549	Metal Contoured Matrices for Premolars Combined with Clamp
1.551	Metal Contoured Matrices for Molars Combined with Clamp
1.552	Metal Contoured Matrices for Molars Combined with Clamp
1.553	Metal Contoured Matrices for Molars Combined with Clamp
1.554	Metal Contoured Matrices for Molars Combined with Clamp
1.555	Metal Contoured Matrices for Molars Combined with Clamp
1.559	Metal Contoured Matrices for Molars Combined with Clamp
1.540	Metal Contoured Matrices for Premolars Combined with Clamp
1.550	Metal Contoured Matrices for Molars Combined with Clamp
1.560	Metal Contoured Matrices for Molars and Premolars Combined with Clamp
1.341	Metal Contoured Matrices «Pony» Small with Ledge
1.342	Metal Contoured Matrices «Pony» Small
1.343	Metal Contoured Matrices «Pony» Large
1.344	Metal Contoured Matrices «Pony» Large with Ledge
1.340	Metal Contoured Matrices «Pony»
1.350	Metal Contoured Matrices «Pony»
1.331 (1)	Perforated Metal Matrix Bands
1.331 (2)	Perforated Metal Matrix Bands
1.331 (3)	Perforated Metal Matrix Bands
1.331 (4)	Perforated Metal Matrix Bands
1.331 (5)	Perforated Metal Matrix Bands
1.531(1)	Contoured Perforated Metal Matrices
1.531(2)	Contoured Perforated Metal Matrices
1.531(3)	Contoured Perforated Metal Matrices
1.531(4)	Contoured Perforated Metal Matrices
1.531(5)	Contoured Perforated Metal Matrices
1.301(1)	Saddle Metal Matrices Small
1.301(2)	Saddle Metal Matrices Small
1.301(3)	Saddle Metal Matrices Small
1.301(4)	Saddle Metal Matrices Small
1.302(1)	Saddle Metal Matrices Medium
1.302(2)	Saddle Metal Matrices Medium
1.302(3)	Saddle Metal Matrices Medium
1.302(4)	Saddle Metal Matrices Medium
1.303(1)	Saddle Metal Matrices Large
1.303(2)	Saddle Metal Matrices Large
1.303(3)	Saddle Metal Matrices Large
1.303(4)	Saddle Metal Matrices Large
1.311(1)	Saddle Contoured Metal Matrices Small
1.311(2)	Saddle Contoured Metal Matrices Small
1.311(3)	Saddle Contoured Metal Matrices Small
1.311(4)	Saddle Contoured Metal Matrices Small
1.312(1)	Saddle Contoured Metal Matrices Medium
1.312(2)	Saddle Contoured Metal Matrices Medium
1.312(3)	Saddle Contoured Metal Matrices Medium
1.312(4)	Saddle Contoured Metal Matrices Medium
1.313(1)	Saddle Contoured Metal Matrices Large
1.313(2)	Saddle Contoured Metal Matrices Large
1.313(3)	Saddle Contoured Metal Matrices Large
1.313(4)	Saddle Contoured Metal Matrices Large



List of Products. Continued

Catalogue number	Product name
1.310	Saddle Metal Matrices
1.320	Saddle Metal Matrices
1.330	Saddle Metal Matrices. Universal Kit
1.0971(10)	Sectional Contoured Metal Matrices Small with Ledge
1.0972(10)	Sectional Contoured Metal Matrices Small
1.0973(10)	Sectional Contoured Metal Matrices Large
1.0974(10)	Sectional Contoured Metal Matrices Large with Ledge
1.0975(10)	Sectional Contoured Metal Matrices Medium with Ledge
1.0976(10)	Sectional Contoured Metal Matrices Medium
1.0971T(10)	Sectional Contoured Metal Titanium Matrices Small with Ledge
1.0972T(10)	Sectional Contoured Metal Titanium Matrices Small
1.0973T(10)	Sectional Contoured Metal Titanium Matrices Large
1.0974T(10)	Sectional Contoured Metal Titanium Matrices Large with Ledge
1.0975T(10)	Sectional Contoured Metal Titanium Matrices Medium with Ledge
1.0976T(10)	Sectional Contoured Metal Titanium Matrices Medium
1.0971DC(10)	Sectional Contoured Metal Double Curved Matrices Small with Ledge
1.0972DC(10)	Sectional Contoured Metal Double Curved Matrices Small
1.0973DC(10)	Sectional Contoured Metal Double Curved Matrices Large
1.0974DC(10)	Sectional Contoured Metal Double Curved Matrices Large with Ledge
1.0975DC(10)	Sectional Contoured Metal Double Curved Matrices Medium with Ledge
1.0976DC(10)	Sectional Contoured Metal Double Curved Matrices Medium
1.0971(50)	Sectional Contoured Metal Matrices Small with Ledge
1.0972(50)	Sectional Contoured Metal Matrices Small
1.0973(50)	Sectional Contoured Metal Matrices Large
1.0974(50)	Sectional Contoured Metal Matrices Large with Ledge
1.0975(50)	Sectional Contoured Metal Matrices Medium with Ledge
1.0976(50)	Sectional Contoured Metal Matrices Medium
1.0971T(50)	Sectional Contoured Metal Titanium Matrices Small with Ledge
1.0972T(50)	Sectional Contoured Metal Titanium Matrices Small
1.0973T(50)	Sectional Contoured Metal Titanium Matrices Large
1.0974T(50)	Sectional Contoured Metal Titanium Matrices Large with Ledge
1.0975T(50)	Sectional Contoured Metal Titanium Matrices Medium with Ledge
1.0976T(50)	Sectional Contoured Metal Titanium Matrices Medium
1.0971DC(50)	Sectional Contoured Metal Double Curved Matrices Small with Ledge
1.0972DC(50)	Sectional Contoured Metal Double Curved Matrices Small
1.0973DC(50)	Sectional Contoured Metal Double Curved Matrices Large
1.0974DC(50)	Sectional Contoured Metal Double Curved Matrices Large with Ledge
1.0975DC(50)	Sectional Contoured Metal Double Curved Matrices Medium with Ledge
1.0976DC(50)	Sectional Contoured Metal Double Curved Matrices Medium
1.1972	Sectional Contoured Metal Matrices Small
1.1973	Sectional Contoured Metal Matrices Large
1.1976	Sectional Contoured Metal Matrices Medium
1.097	Sectional Contoured Metal Matrices
1.098	Sectional Contoured Metal Matrices
1.098T	Sectional Contoured Metal Titanium Matrices
1.098DC	Sectional Contoured Metal Double Curved Matrices
1.198	Sectional Contoured Metal Matrices
1.298	Sectional Contoured Metal Matrices
1.398	Sectional Contoured Metal Matrices



List of Products. Continued

Catalogue number	Product name
1.498	Sectional Contoured Metal Matrices
1.351(1)	Lug Matrices
1.352(1)	Lug Matrices
1.353(1)	Lug Matrices
1.351(2)	Lug Matrices
1.352(2)	Lug Matrices
1.353(2)	Lug Matrices
1.351	Lug Matrices Small with Ledge
1.352	Lug Matrices Medium with Ledge
1.353	Lug Matrices Large with Ledge
1.353L	Lug Matrices Large with Ledge
2.351	Lug Matrices Small
2.352	Lug Matrices Medium
2.353	Lug Matrices Large
1.338	Lug Matrices
1.348	Lug Matrices
1.368	Lug Matrices
1.387	Proximal Anterior Strips
1.387A	Proximal Anterior Strips
1.388	Proximal Anterior Strips
1.521	Twin Anterior Matrices
1.522	Twin Anterior Matrices
1.523	Twin Anterior Matrices
1.523A	Twin Anterior Matrices
1.533	Twin Anterior Matrices
1.533A	Twin Anterior Matrices
1.888	Anterior Matrices and Strips
Transparent Matrices	
1.040	Transparent Strips
1.041	Transparent Strips
1.042	Transparent Strips
1.440	Transparent Stopstrips
1.441	Transparent Stopstrips
1.240	Transparent Striproll
1.241	Transparent Striproll
1.242	Transparent Striproll
1.243	Transparent Striproll
1.244	Transparent Striproll with Cutting Plate
1.245	Transparent Striproll with Cutting Plate
1.090(1)	Transparent Contoured Matrices for Premolars
1.090(2)	Transparent Contoured Matrices for Premolars
1.090(3)	Transparent Contoured Matrices for Premolars
1.090(3/4)	Transparent Contoured Matrices for Premolars
1.090(4)	Transparent Contoured Matrices for Premolars
1.091(1)	Transparent Contoured Matrices for Molars
1.091(2)	Transparent Contoured Matrices for Molars
1.091(3)	Transparent Contoured Matrices for Molars
1.091(3/4)	Transparent Contoured Matrices for Molars
1.091(4)	Transparent Contoured Matrices for Molars
1.190	Transparent Contoured Matrices for Premolars



List of Products. Continued

Catalogue number	Product name
1.191	Transparent Contoured Matrices for Molars
1.092	Transparent Contoured Matrices. Universal Kit for Molars and Premolars
1.490(1)	Transparent Contoured Self-Adhesive Matrices for Premolars
1.490(2)	Transparent Contoured Self-Adhesive Matrices for Premolars
1.490(3)	Transparent Contoured Self-Adhesive Matrices for Premolars
1.490(3/4)	Transparent Contoured Self-Adhesive Matrices for Premolars
1.490(4)	Transparent Contoured Self-Adhesive Matrices for Premolars
1.491(1)	Transparent Contoured Self-Adhesive Matrices for Molars
1.491(2)	Transparent Contoured Self-Adhesive Matrices for Molars
1.491(3)	Transparent Contoured Self-Adhesive Matrices for Molars
1.491(3/4)	Transparent Contoured Self-Adhesive Matrices for Molars
1.491(4)	Transparent Contoured Self-Adhesive Matrices for Molars
1.922	Transparent Contoured Matrices Sectional Narrow
1.923	Transparent Contoured Matrices Sectional Wide
1.046L	Transparent Matrices for Anteriors
1.910	Anterior Transparent Crowns
1.911	Posterior Transparent Crowns
1.912	Deciduous Transparent Crowns
1.915	Conical Transparent Crowns
1.901	Transparent Crowns
1.903	Transparent Crowns
1.905	Transparent Crowns
1.907	Transparent Crowns
1.908	Transparent Crowns
1.909	Transparent Crowns
1.034	Plastic-Metal Combined Matrix Bands for Premolars
1.134	Plastic-Metal Combined Matrix Bands for Molars
1.141	Transparent Cervical Matrix Bands
1.094(1)	Transparent Contoured Matrices Combined with Clamp for Premolars
1.094(2)	Transparent Contoured Matrices Combined with Clamp for Premolars
1.094(3)	Transparent Contoured Matrices Combined with Clamp for Premolars
1.094(3/4)	Transparent Contoured Matrices Combined with Clamp for Premolars
1.094(4)	Transparent Contoured Matrices Combined with Clamp for Premolars
1.095(1)	Transparent Contoured Matrices Combined with Clamp for Molars
1.095(2)	Transparent Contoured Matrices Combined with Clamp for Molars
1.095(3)	Transparent Contoured Matrices Combined with Clamp for Molars
1.095(3/4)	Transparent Contoured Matrices Combined with Clamp for Molars
1.095(4)	Transparent Contoured Matrices Combined with Clamp for Molars
1.095(2+)	Transparent Contoured Matrices Combined with Clamp for Gross Molars
1.194	Transparent Contoured Matrices Combined with Clamp for Premolars
1.195	Transparent Contoured Matrices Combined with Clamp for Molars
1.096	Transparent Contoured Matrices Combined with Clamp for Premolars and Molars

Dr. Oleg Mikhalev,
General manager
January 10, 2022

