



Dental Manufacturing Company
Novatorov str., 7A bld.2, Moscow 119421, Russia
e-mail: torvm77@gmail.com

Phone/fax: +7(495) 225 54 17
internet: www.torvm.ru

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 Metal Matrices
463003499PLCMATB8 Transparent Matrices

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: TOR VM uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:
Class I: EC conformity declaration according to Annex IV, Rule 5 and
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 10993-12:2012, EN ISO 10993-18:2009, EN 62366-1:2008, BS EN ISO 15223-1:2016

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) MDR 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:

.....
Dr. Oleg Mikhalev
General manager



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

Moscow, Russia
27.12.2021



Annex to Declaration of Conformity
page 1 of 7

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
1.0928	Metal Sub-Gingival Matrix Bands
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
1.2932	Metal Matrix Bands for Molars
1.936	Metal Matrix Bands for Anteriors
1.937	Metal Matrix Bands for Anteriors
1.938	Metal Matrix Bands for Anteriors
1.939	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
1.378	Metal Strips
1.379	Metal Strips
1.390	Metal Striproll
1.391	Metal Striproll
1.392	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



List of Products. Continued

Catalogue number	Product name
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
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
1.540	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



List of Products. Continued

Catalogue number	Product name
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
1.310	Saddle Metal Matrices
1.320	Saddle Metal Matrices
1.330	Saddle Metal Matrices. Universal Kit
1.0971	Sectional Contoured Metal Matrices Small with Ledge
1.0972	Sectional Contoured Metal Matrices Small
1.0973	Sectional Contoured Metal Matrices Large
1.0974	Sectional Contoured Metal Matrices Large with Ledge
1.0975	Sectional Contoured Metal Matrices Medium with Ledge
1.0976	Sectional Contoured Metal Matrices Medium
1.0971T	Sectional Contoured Metal Titanium Matrices Small with Ledge
1.0972T	Sectional Contoured Metal Titanium Matrices Small
1.0973T	Sectional Contoured Metal Titanium Matrices Large
1.0974T	Sectional Contoured Metal Titanium Matrices Large with Ledge
1.0975T	Sectional Contoured Metal Titanium Matrices Medium with Ledge
1.0976T	Sectional Contoured Metal Titanium Matrices Medium
1.0971DC	Sectional Contoured Metal Double Curved Matrices Small with Ledge
1.0972DC	Sectional Contoured Metal Double Curved Matrices Small
1.0973DC	Sectional Contoured Metal Double Curved Matrices Large
1.0974DC	Sectional Contoured Metal Double Curved Matrices Large with Ledge
1.0975DC	Sectional Contoured Metal Double Curved Matrices Medium with Ledge
1.0976DC	Sectional Contoured Metal Double Curved Matrices Medium
1.971	Sectional Contoured Metal Matrices Small with Ledge
1.972	Sectional Contoured Metal Matrices Small
1.973	Sectional Contoured Metal Matrices Large
1.974	Sectional Contoured Metal Matrices Large with Ledge
1.975	Sectional Contoured Metal Matrices Medium with Ledge
1.976	Sectional Contoured Metal Matrices Medium
1.971T	Sectional Contoured Metal Titanium Matrices Small with Ledge
1.972T	Sectional Contoured Metal Titanium Matrices Small
1.973T	Sectional Contoured Metal Titanium Matrices Large
1.974T	Sectional Contoured Metal Titanium Matrices Large with Ledge
1.975T	Sectional Contoured Metal Titanium Matrices Medium with Ledge
1.976T	Sectional Contoured Metal Titanium 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
1.398T	Sectional Contoured Metal Titanium Matrices
1.498	Sectional Contoured Metal Matrices
1.498T	Sectional Contoured Metal Titanium Matrices



List of Products. Continued

Catalogue number	Product name
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
1.351T	Lug Titanium Matrices Small with Ledge
1.352T	Lug Titanium Matrices Medium with Ledge
1.353T	Lug Titanium Matrices Large with Ledge
1.353LT	Lug Titanium Matrices Large with Ledge
2.351T	Lug Titanium Matrices Small
2.352T	Lug Titanium Matrices Medium
2.353T	Lug Titanium Matrices Large
1.338	Lug Matrices
1.348	Lug Matrices
1.368	Lug Matrices
1.368T	Lug Titanium Matrices
1.387	Proximal Anterior Strips
1.387A	Proximal Anterior Strips
1.388	Proximal Anterior Strips
1.387AT	Proximal Anterior Titanium Strips
1.387T	Proximal Anterior Titanium Strips
1.388T	Proximal Anterior Titanium 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
1.521T	Twin Anterior Titanium Matrices
1.522T	Twin Anterior Titanium Matrices
1.523T	Twin Anterior Titanium Matrices
1.523AT	Twin Anterior Titanium Matrices
1.533T	Twin Anterior Titanium Matrices
1.533AT	Twin Anterior Titanium Matrices
1.888	Anterior Matrices and Strips



List of Products. Continued

Catalogue number	Product name
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
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
1.223	Transparent Matrices for Anteriors
1.233	Transparent Matrices for Anteriors
1.046	Transparent Matrices for Anteriors
1.047	Transparent Matrices for Anteriors
1.048	Transparent Matrices for Anteriors
1.049	Transparent Matrices for Anteriors
1.951	Transparent Contoured Matrices for Anteriors
1.952	Transparent Contoured Matrices for Anteriors
1.953	Transparent Contoured Matrices for Anteriors
1.954	Transparent Contoured Matrices for Anteriors
1.955	Transparent Contoured Matrices for Anteriors
1.956	Transparent Contoured Matrices for Anteriors



List of Products. Continued

Catalogue number	Product name
1.957	Transparent Contoured Matrices for Anteriors
1.958R	Transparent Contoured Matrices for Anteriors
1.958L	Transparent Contoured Matrices for Anteriors
1.959R	Transparent Contoured Matrices for Anteriors
1.959L	Transparent Contoured Matrices for Anteriors
1.950	Transparent Contoured Matrices for Anteriors
1.423	Transparent Contoured Matrices for Anteriors
1.433	Transparent Contoured 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
1.9 (11 21)L	Anterior Crowns Upper Large
1.9 (11 21)S	Anterior Crowns Upper Small
1.9 (11 21)M	Anterior Crowns Upper Medium
1.9 (12 22)L	Anterior Crowns Upper Large
1.9 (12 22)M	Anterior Crowns Upper Medium
1.9 (12 22)S	Anterior Crowns Upper Small
1.9 (13 23)L	Anterior Crowns Upper Large
1.9 (13 23)M	Anterior Crowns Upper Medium
1.9 (13 23)S	Anterior Crowns Upper Small
1.9 (14 24)S	Posterior Crowns Upper Small
1.9 (14 24)M	Posterior Crowns Upper Medium
1.9 (15 25)S	Posterior Crowns Upper Small
1.9 (15 25)M	Posterior Crowns Upper Medium
1.9 (16 26)S	Posterior Crowns Upper Small
1.9 (16 26)M	Posterior Crowns Upper Medium
1.9 (17 27)S	Posterior Crowns Upper Small
1.9 (17 27)M	Posterior Crowns Upper Medium
1.9 (31 41)L	Anterior Crowns Lower Large
1.9 (31 41)M	Anterior Crowns Lower Medium
1.9 (312 412)S	Anterior Crowns Lower Small
1.9 (32 42)L	Anterior Crowns Lower Large
1.9 (32 42)M	Anterior Crowns Lower Medium
1.9 (33 43)M	Anterior Crowns Lower Medium
1.9 (33 43)S	Anterior Crowns Lower Small
1.9 (34 44)M	Posterior Crowns Lower Medium
1.9 (34 44)S	Posterior Crowns Lower Small
1.9 (35 45)M	Posterior Crowns Lower Medium
1.9 (35 45)S	Posterior Crowns Lower Small
1.9 (36 46)M	Posterior Crowns Lower Medium
1.9 (36 46)S	Posterior Crowns Lower Small
1.9 (37 47)M	Posterior Crowns Lower Medium



List of Products. Continued

Catalogue number	Product name
1.9 (37 47)S	Posterior Crowns Lower Small
1.9 (51 61)L	Deciduous Crowns Upper Large
1.9 (51 61)M	Deciduous Crowns Upper Medium
1.9 (51 61)S	Deciduous Crowns Upper Small
1.9 (52 62)L	Deciduous Crowns Upper Large
1.9 (52 62)M	Deciduous Crowns Upper Medium
1.9 (52 62)S	Deciduous Crowns Upper Small
1.9 (53 63)M	Deciduous Crowns Upper Medium
1.9 (53 63)S	Deciduous Crowns Upper Small
1.9 (54 64)M	Deciduous Crowns Upper Medium
1.9 (54 64)S	Deciduous Crowns Upper Small
1.9 (55 65)M	Deciduous Crowns Upper Medium
1.9 (55 65)S	Deciduous Crowns Upper Small
1.9 (74 84)M	Deciduous Crowns Lower Medium
1.9 (74 84)S	Deciduous Crowns Lower Small
1.9 (75 85)M	Deciduous Crowns Lower Medium
1.9 (75 85)S	Deciduous Crowns Lower Small
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
December 27, 2021

