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Declaration of Conformity

Manufacturer: **TOR VM**
Address: Novatorov str., 7A, bld.2, Moscow 119421
Manufacturing site: Kulibina, 15s, Voronezh, 394000
Country: Russia
Telephone No. +7 495 2255417

Product **Matrix Bands**
(Annex specifying List of Products is an integral part of this Declaration)

The undersigned hereby declares, on behalf of the TOR VM, Novatorov str., 7A, bld.2, Moscow 119421, Russia, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:

Council Directive 93/42 EEC (Class I, Rule 5), Annex VII,
Assessment procedure according to Annex IX, Rule 5 MDD 93/42,
and

EN 1041:2008, EN ISO 13485:2012, EN ISO 14971:2012, EN 1639:2009, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-11:2017, EN ISO 10993-12:2012, EN 62366:2015, BS EN ISO 15223-1:2012.

The technical construction file required by MDD 93/42 directive is maintained at the corporate headquarters of **TOR VM** Novatorov str., 7A, bld.2, Moscow, 119421, Russia, and its official EC representative **Mr. Gregor Kostunov**, Address: Untere Seegasse 54, DE-69124 Heidelberg, Germany.

Notified Body for Class I not relevant.

UMDNS Codes 16-195 Matrix Bands, Dental

Date of the first CE mark: 10.08.2005
Valid: unlimited
Place of issue: Moscow, Russia
Date of issue: 10.08.2005
Version 5 of 15.05.2019

Dr. Oleg Mikhalev
General manager



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List of Products

Catalogue number	Product name
Metal Matrix Bands	
1.0930	Metal Matrix Bands for premolars (without ledge, 7 mm) - 12 pcs.
1.0932	Metal Matrix Bands for premolars (bilateral) - 12 pcs.
1.0933	Metal Matrix Bands for premolars (side ledge) - 12 pcs.
1.0935	Metal Matrix Bands for premolars (one central ledge) - 12 pcs.
1.0931	Metal Matrix Bands for molars (without ledge, 5 mm) - 12 pcs.
1.1932	Metal Matrix Bands for molars shape 2 - 12 pcs.
1.1933	Metal Matrix Bands for molars shape 3 - 12 pcs.
1.1935	Metal Matrix Bands for molars shape 5 - 12 pcs.
1.1937	Metal Matrix Bands for molars (without ledge, 6 mm) - 12 pcs.
1.380	Matrix Bands 6 mm wide - 12 pcs.
1.381	Matrix Bands 7 mm wide - 12 pcs.
1.382	Metal Strips 0,06 mm thick - 100 pcs.
1.383	Metal Strips 0,07 mm thick - 100 pcs.
1.390	Metal Striproll 5 or 6 mm wide, 3 m in length (round package)
1.391	Metal Striproll 7 or 8 mm wide, 3 m in length (round package)
1.392	Metal Striproll 5 or 6 mm wide, 3 m in length (squared package)
1.393	Metal Striproll 7 or 8 mm wide, 3 m in length (squared package)
1.595	Loop Matrices, height 5 mm - 6 pcs.
1.597	Loop Matrices, height 7 mm - 6 pcs.
1.501	Metal Contoured Matrices for premolars (without ledge) - 12 pcs.
1.502	Metal Contoured Matrices for premolars (bilateral) - 12 pcs.
1.503	Metal Contoured Matrices for premolars (left ledge) - 12 pcs.
1.504	Metal Contoured Matrices for premolars (right ledge) - 12 pcs.
1.505	Metal Contoured Matrices for premolars (one central ledge) - 12 pcs.
1.506	Metal Contoured Matrices for premolars (bilateral) - 12 pcs.
1.511	Metal Contoured Matrices for molars (without ledge) - 12 pcs.
1.512	Metal Contoured Matrices for molars (bilateral) - 12 pcs.
1.513	Metal Contoured Matrices for molars (left ledge) - 12 pcs.
1.514	Metal Contoured Matrices for molars (right ledge) - 12 pcs.
1.515	Metal Contoured Matrices for molars (one central ledge) - 12 pcs.
1.517	Metal Contoured Matrices for molars (without ledge) - 12 pcs.
1.500	Metal Contoured Matrices for premolars, 24 pcs.: 1.501 - 6 pcs., 1.502 - 6 pcs., 1.503 - 6 pcs., 1.504 - 6 pcs.
1.500+	Metal Contoured Matrices for premolars, 30 pcs.: 1.501 - 6 pcs., 1.502 - 6 pcs., 1.503 - 6 pcs., 1.504 - 6 pcs., 1.505 - 6 pcs.
1.510	Metal Contoured Matrices for molars, 24 pcs.: 1.511 - 6 pcs., 1.512 - 6 pcs., 1.513 - 6 pcs., 1.514 - 6 pcs.
1.510+	Metal Contoured Matrices for molars, 30 pcs.: 1.511 - 6 pcs., 1.512 - 6 pcs., 1.513 - 6 pcs., 1.514 - 6 pcs., 1.515 - 6 pcs.
1.541	Metal Contoured Matrices Combined with Clamp for premolars (one central ledge)- 12 pcs.
1.542	Metal Contoured Matrices Combined with Clamp for premolars (bilateral) - 12 pcs.
1.543	Metal Contoured Matrices Combined with Clamp for premolars (left ledge) - 12 pcs.
1.544	Metal Contoured Matrices Combined with Clamp for premolars (right ledge) - 12 pcs.



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List of Products. Continued

Catalogue number	Product name
1.545	Metal Contoured Matrices Combined with Clamp for premolars (without ledge) - 12 pcs.
1.549	Metal Contoured Matrices Combined with Clamp for premolars (left & right ledge)- 12pcs.
1.551	Metal Contoured Matrices Combined with Clamp for molars (one central ledge) - 12 pcs.
1.552	Metal Contoured Matrices Combined with Clamp for molars (bilateral) - 12 pcs.
1.553	Metal Contoured Matrices Combined with Clamp for molars (left ledge) - 12 pcs.
1.554	Metal Contoured Matrices Combined with Clamp for molars (right ledge) - 12 pcs.
1.555	Metal Contoured Matrices Combined with Clamp for molars (without ledge) - 12 pcs.
1.559	Metal Contoured Matrices Combined with Clamp for molars (left & right ledge)- 12 pcs.
1.540	Metal Contoured Matrices Combined with Clamp for premolars, 16 pcs.: 1.541 - 3 pcs., 1.542 - 3 pcs., 1.543 - 3 pcs., 1.544 - 3 pcs., 1.545 - 4 pcs.
1.550	Metal Contoured Matrices Combined with Clamp for molars, 16 pcs.: 1.551 - 3 pcs., 1.552 - 3 pcs., 1.553 - 3 pcs., 1.554 - 3 pcs., 1.555 - 4 pcs.
1.560	Metal Contoured Matrices Combined with Clamp for premolars & molars (without ledge), 10 pcs.: 1.545 - 5 pcs., 1.555 - 5 pcs.
1.341	Pony Metal Contoured Matrices, small with ledge - 12 pcs.
1.342	Pony Metal Contoured Matrices, small - 12 pcs.
1.343	Pony Metal Contoured Matrices, large - 12 pcs.
1.344	Pony Metal Contoured Matrices, large with ledge - 12 pcs.
1.340	Pony Metal Contoured Matrices. Kit with Slot springclip. 24 pcs.: 1.341 - 6 pcs., 1.342 - 6 pcs., 1.343 - 6 pcs., 1.344 - 6 pcs., slot springclip - 1 pc.
1.350	Pony Metal Contoured Matrices. Kit with Slot ring. 24 pcs.: 1.341 - 6 pcs., 1.342 - 6 pcs., 1.343 - 6 pcs., 1.344 - 6 pcs., slot ring - 1 pc.
1.331	Perforated Metal Matrices of one of the shape - 12 pcs.
1.531	Perforated Contoured Metal Matrices of one of the shape - 12 pcs.
1.301	Saddle Metal Matrices, small - 12 pcs.
1.302	Saddle Metal Matrices, medium - 12 pcs.
1.303	Saddle Metal Matrices, large - 12 pcs.
1.311	Saddle Contoured Metal Matrices, small - 12 pcs.
1.312	Saddle Contoured Metal Matrices, medium - 12 pcs.
1.313	Saddle Contoured Metal Matrices, large - 12 pcs.
1.310	Saddle Metal Matrices. Kit with springclip. 18 pcs.: 1.311 - 6 pcs., 1.312 - 6 pcs., 1.313 - 6 pcs., springclip - 1 pc.
1.320	Saddle Metal Matrices. Kit with ring. 18 pcs.: 1.311 - 6 pcs., 1.312 - 6 pcs., 1.313 - 6 pcs., ring - 1 pc.
1.330	Saddle Metal Matrices. Universal Kit. 36 pcs.: 1.301 - 3 pcs., 1.302 - 3 pcs., 1.303 - 3 pcs., 1.311 - 9 pcs., 1.312 - 9 pcs., 1.313 - 9 pcs., springclip - 1 pc.
1.0971	Sectional Contoured Metal Matrices, small with ledge – 10 or 50 pcs.
1.0972	Sectional Contoured Metal Matrices, small – 10 or 50 pcs.
1.0973	Sectional Contoured Metal Matrices, large – 10 or 50 pcs.
1.0974	Sectional Contoured Metal Matrices, large with ledge – 10 or 50 pcs.
1.0975	Sectional Contoured Metal Matrices, medium with ledge – 10 or 50 pcs.
1.0976	Sectional Contoured Metal Matrices, medium – 10 or 50 pcs.



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List of Products. Continued

Catalogue number	Product name
1.1972	Sectional Contoured Metal Matrices, small, 4 types of metal quality – 30 pcs.
1.1973	Sectional Contoured Metal Matrices, large, 4 types of metal quality – 30 pcs.
1.1976	Sectional Contoured Metal Matrices, medium, 4 types of metal quality – 30 pcs.
1.097	Sectional Contoured Metal Matrices, 15 pcs.: 1.0971 – 5 pcs., 1.0972 – 10 pcs.
1.098	Sectional Contoured Metal Matrices, 25 pcs.: 1.0972 – 10 pcs., 1.0973 – 10 pcs., 1.0974 – 5 pcs.
1.198	Sectional Contoured Metal Matrices, 30 pcs.: 1.0971 – 3 pcs., 1.0972 – 10 pcs., 1.0973 – 5 pcs., 1.0974 – 3 pcs., 1.0975 – 4 pcs., 1.0976 – 5 pcs., ring – 1 pc.
1.298	Sectional Contoured Metal Matrices, 50 pcs.: 1.0971 – 5 pcs., 1.0972 – 15 pcs., 1.0973 – 10 pcs., 1.0974 – 5 pcs., 1.0975 – 5 pcs., 1.0976 – 10 pcs., ring – 1 pc.
1.398	Sectional Contoured Metal Matrices, 100 pcs.: 1.0971 – 10 pcs., 1.0972 – 20 pcs., 1.0973 – 20 pcs., 1.0974 – 10 pcs., 1.0975 – 10 pcs., 1.0976 – 30 pcs., rings – 2 pc.
1.351(1)	Lug matrices (one lug), small 12 pcs.
1.352(1)	Lug matrices (one lug), medium 12 pcs.
1.353(1)	Lug matrices (one lug), large 12 pcs.
1.351(2)	Lug matrices (three lugs), small 12 pcs.
1.352(2)	Lug matrices (three lugs), medium 12 pcs.
1.353(2)	Lug matrices (three lugs), large 12 pcs.
1.358	Lug matrices (one lug), 18 pcs.: 1.351(1) – 6 pcs., 1.352(1) – 6 pcs., 1.353(1) – 6 pcs., MD ring – 1 pc.
1.368	Lug matrices (three lugs), 18 pcs.: 1.351(2) – 6 pcs., 1.352(2) – 6 pcs., 1.353(2) – 6 pcs., MD ring – 1 pc.
1.387	Proximal Anterior Strips, small - 12 pcs.
1.387A	Proximal Anterior Strips, 5 mm - 12 pcs.
1.388	Proximal Anterior Strips, large - 12 pcs.
1.523	Twin Anterior Matrices – 12 pcs.
Plastic Matrix Bands	
1.040	Transparent Strips, 8 mm wide, 95 mm long - 100 pcs.
1.041	Transparent Strips, 10 mm wide, 95 mm long - 100 pcs.
1.440	Transparent Stopstrips, 8 mm wide, 95 mm long - 12 pcs.
1.441	Transparent Stopstrips, 10 mm wide, 95 mm long - 12 pcs.
1.240	Transparent Striproll, 8 mm wide, 10 m long (in round box)
1.241	Transparent Striproll, 10 mm wide, 10 m long (in round box)
1.242	Transparent Striproll, 8 mm wide, 10 m long (in squared box)
1.243	Transparent Striproll, 10 mm wide, 10 m long (in squared box)
1.244	Transparent Striproll, 8 mm wide, 10 m long (in squared box with cutting plate)
1.245	Transparent Striproll, 10 mm wide, 10 m long (in squared box with cutting plate)
1.090	Transparent Contoured Matrices for premolars of 1 of 4 shapes - 30 pcs.
1.091	Transparent Contoured Matrices for molars of 1 of 4 shapes - 30 pcs.
1.190	Transparent Contoured Matrices for Premolars. Universal Kit. 60 pcs.
1.191	Transparent Contoured Matrices for Molars. Universal Kit. 60 pcs.
1.092	Transparent Contoured Matrices for Premolars and Molars. Universal Kit. 120 pcs.



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Catalogue number	Product name
1.490	Self-Adhesive Transparent Contoured Matrices for premolars, matrices of 1 of 4 shapes - 12 pcs.
1.491	Self-Adhesive Transparent Contoured Matrices for molars, matrices of 1 of 4 shapes - 12 pcs.
1.922	Transparent Sectional Contoured Matrices (narrow, width 5 mm) - 30 pcs.
1.923	Transparent Sectional Contoured Matrices (wide, width 7 mm) - 30 pcs.
1.910	Anterior Transparent Crowns - 64 pcs.
1.911	Posterior Transparent Crowns - 64 pcs.
1.912	Deciduous Transparent Crowns - 64 pcs.
1.915	Conical Transparent Crowns - 64 pcs.
1.901	Transparent Crowns for Coronal Part of Incisors - 12 pcs.
1.903	Transparent Crowns for Frontal Surface of Incisors - 16 pcs.
1.905	Transparent Crowns for Approximal Surface of Small and Medium Incisors and Canines - 17 pcs.
1.907	Transparent Crowns for Approximal Surface of Medium and Large Incisors and Canines - 18 pcs.
1.908	Transparent Crowns for Molars and Premolars -12 pcs.
1.909	Transparent Crowns for Coronal Part of Incisors, Canines and Premolars - 12 pcs.
Plastic-Metal Matrix Bands	
1.034	Plastic-Metal Combined Matrix Bands for premolars - 12 pcs.
1.134	Plastic-Metal Combined Matrix Bands for molars - 12 pcs.
1.141	Transparent Cervical Matrix Bands: matrix bands 10x37 mm - 100pcs., cervical former - 1 pc., stopper - 1 pc.
1.094	Transparent Contoured Matrices Combined with Clamp for premolars of 1 of 4 shapes - 10 pcs.
1.095	Transparent Contoured Matrices Combined with Clamp for molars of 1 of 4 shapes - 10 pcs.
1.095(2+)	Transparent Contoured Matrices Combined with Clamp for gross molars (bilateral) - 10 pcs.
1.194	Transparent Contoured Matrices Combined with Clamp for Premolars. Universal Kit. 16 pcs.
1.195	Transparent Contoured Matrices Combined with Clamp for Molars. Universal Kit. 16 pcs.
1.096	Transparent Contoured Matrices Combined with Clamp for Premolars and Molars. Universal Kit. 32 pcs.

Dr. Oleg Mikhalev
General manager
May 15, 2019