



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

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

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 Wedges**
(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 16-370 Matrix Wedges, 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 01.07.2019

Dr. Oleg Mikhalev
General manager



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Annex to Declaration of Conformity

List of Products

Catalogue number	Product name
Wooden Wedges	
1.181	Wooden Wedges, superthin, short (orange) - 100 pcs.
1.182	Wooden Wedges, thin, short (white) - 100 pcs.
1.183	Wooden Wedges, thin, short (green) - 100 pcs.
1.184	Wooden Wedges, thin, long (yellow) - 100 pcs.
1.185	Wooden Wedges, medium, short (blue) - 100 pcs.
1.186	Wooden Wedges, medium, long (pink) - 100 pcs.
1.187	Wooden Wedges, thick, long (violet) - 100 pcs.
1.080	Wooden Wedges of 2 types - 100 pcs.
1.083	Wooden Wedges of 4 types - 200 pcs.: 1.182 - 50 pcs., 1.184 - 50 pcs., 1.185 - 50 pcs., 1.186 - 50 pcs.
1.085	Wooden Wedges of 6 types - 400 pcs.: 1.181 - 100 pcs., 1.182 - 100 pcs., 1.184 - 50 pcs., 1.185 - 50 pcs., 1.186 - 50 pcs., 1.187 - 50 pcs.
1.281	Triangle Wooden Wedges - 100 pcs.
Transparent Plastic Wedges	
1.811	Transparent Wedges, thin - 40 pcs.
1.812	Transparent Wedges, medium - 40 pcs.
1.810	Transparent Wedges of 2 types - 40 pcs. 1.811 - 25 pcs., 1.812 - 15 pcs.
1.820	Transparent Wedges of 2 types - 80 pcs. 1.811 - 50 pcs., 1.812 - 30 pcs.
Non-Transparent Plastic Wedges	
1.841	Non-Transparent Wedges, thin - 40 pcs.
1.842	Non-Transparent Wedges, medium - 40 pcs.
1.840	Non-Transparent Wedges of 2 types - 80 pcs. 1.841 - 50 pcs., 1.842 - 30 pcs.
Elastic Wedges	
1.801	Elastic Wedges, 2,5 mm thick - 10 pcs.
1.802	Elastic Wedges, 2,0 mm thick - 10 pcs.
1.808	Elastic Wedges of 2 types - 40 pcs. 1.801 - 20 pcs., 1.802 - 20 pcs.
Add-On Wedges and Tubes	
1.861	Add-On Wedges - 40 pcs.
1.862	Add-On Tubes of 2 types- 40 pcs.: wide (transparent) - 20 pcs., narrow (white) - 20 pcs.
1.866	Add-On Wedges - 40 pcs.
Shape-Former Caps	
1.863	Shape-Former Caps - 10 pcs
1.867	Shape-Former Caps - 10 pcs
1.868	Shape-Former Caps - 10 pcs

Dr. Oleg Mikhalev
General manager
July 1, 2019