



Declaration of Conformity

Manufacturer: **TOR VM Ltd.**
SRN:
Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421
Manufacturing site: Kulibina, 15c, Voronezh, 394029
Country: Russia
Telephone No. +7 495 2255417

EC representative: Mr. Gregor Kostunov
SRN: DE-AR-000006585
Address: Untere Seegasse 54, DE-69124, Heidelberg
Country: Germany
Telephone: +49 (17) 626 400 019

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, room 44B, Moscow 119421, Russia that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:

Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV,
Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745,
and
EN 1041:2008, EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2020, EN 62366-1:2015, EN 980:2008, BS EN ISO 15223-1:2016.

The technical construction file required by Regulation (EU) 2017/745, is maintained at the corporate headquarters of **TOR VM Ltd.** Novatorov str., 7A, bld. 2, room 44B, Moscow, 119421, and its official EC representative **Mr. Gregor Kostunov**, Address: Untere Seegasse 54, DE-69124 Heidelberg, Germany.

Notified Body for Class I not relevant.

GMDN code 45007, Dental Wedge, Single-Use

Date of the first CE mark: 10.08.2005
Valid: unlimited
Place of issue: Moscow, Russia
Date of issue: 26.05.2021


Dr. Oleg Mikhaley
General manager

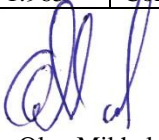




Annex to Declaration of Conformity
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List of Products

Catalogue number	Product name
Wooden Wedges	
1.181	Fixing Wooden Wedges
1.181A	Fixing Wooden Wedges
1.182	Fixing Wooden Wedges
1.183	Fixing Wooden Wedges
1.183A	Fixing Wooden Wedges
1.183B	Fixing Wooden Wedges
1.184	Fixing Wooden Wedges
1.184A	Fixing Wooden Wedges
1.184B	Fixing Wooden Wedges
1.185	Fixing Wooden Wedges
1.185B	Fixing Wooden Wedges
1.186	Fixing Wooden Wedges
1.186A	Fixing Wooden Wedges
1.186B	Fixing Wooden Wedges
1.187	Fixing Wooden Wedges
1.080	Fixing Wooden Wedges
1.083	Fixing Wooden Wedges
1.085	Fixing Wooden Wedges
1.281	Trigonal Fixing Wooden Wedges
1.281(1)	Trigonal Fixing Wooden Wedges
1.281(2)	Trigonal Fixing Wooden Wedges
1.281(3)	Trigonal Fixing Wooden Wedges
1.281(4)	Trigonal Fixing Wooden Wedges
Transparent Plastic Wedges	
1.811	Transparent Fixing Wedges, Thin
1.812	Transparent Fixing Wedges, Medium
1.810	Transparent Fixing Wedges
1.820	Transparent Fixing Wedges
Non-Transparent Plastic Wedges	
1.841	Plastic Fixing Wedges, Thin
1.842	Plastic Fixing Wedges, Medium
1.840	Plastic Fixing Wedges
Elastic Wedges	
1.801	Wedges Elastic, 2,5 mm
1.802	Wedges Elastic, 2,0 mm
1.808	Wedges Elastic
Add-On Wedges and Tubes	
1.861	Add-On Fixing Wedges
1.862	Add-On Fixing Tubes
1.866	Add-On Fixing Wedges
1.870	Fixing Kit Delta
Shape-Former Caps	
1.863	Shape-Former Caps
1.867	Shape-Former Caps
1.868	Shape-Former Caps
1.965	Contact and Shape Former


Dr. Oleg Mikhalev
General manager
May 26, 2021

