



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: 463003499WODWEDG9 / 463003499PLCWEDC6

Name of the Device (s): **Matrix Wedges.** Wooden Wedge / Plastic Wedges
(Annex specifying List of Products is an integral part of this Declaration)

Product code: GMDN 45007, Dental Wedge, 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 ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN 62366:2015, 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
03.08.2022



List of Products

Catalogue number	Product name
Matrix Wedges. Wooden Wedges	
1.181	Fixing Wooden Wedges
1.182	Fixing Wooden Wedges
1.183	Fixing Wooden Wedges
1.184	Fixing Wooden Wedges
1.185	Fixing Wooden Wedges
1.186	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
Matrix Wedges. Plastic Wedges	
1.811	Transparent Fixing Wedges, Thin
1.812	Transparent Fixing Wedges, Medium
1.810	Transparent Fixing Wedges
1.820	Transparent Fixing Wedges
1.841	Plastic Fixing Wedges, Thin
1.842	Plastic Fixing Wedges, Medium
1.840	Plastic Fixing Wedges
1.801	Wedges Elastic, 2,5 mm
1.802	Wedges Elastic, 2,0 mm
1.808	Wedges Elastic
1.861	Add-On Fixing Wedges
1.862	Add-On Fixing Tubes
1.866	Add-On Fixing Wedges
1.870	Fixing Kit Delta
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
August 03, 2022