



## *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.

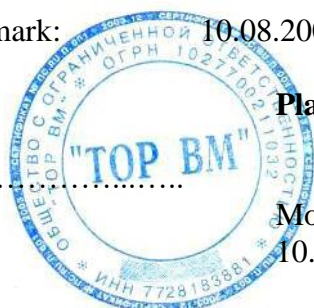
**Conformity assessment route:** Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV, Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745;  
EN 1041:2008, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN 62366-1:2015+A1:2020, 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



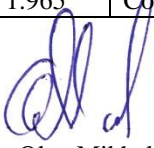
Place and date (dd.mm.yyyy) of issue:

Moscow, Russia  
10.01.2022



List of Products

Catalogue number	Product name
<b>Matrix Wedges. Wooden Wedges</b>	
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
<b>Matrix Wedges. Plastic Wedges</b>	
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  
January 10, 2022

