



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: 463003499SYSMATLE

Name of the Device (s): **Matrix Systems**
(Annex specifying List of Products is an integral part of this Declaration)

Product code: GMDN 38786, Dental Matrix Band, Single-Use
GMDN 35702, Dental Abrasive Strip, Single-Use
GMDN 33204, Dental Matrix Band Retainer
GMDN 45007, Dental Wedge, Single-Use

Classification: Class I, Rule 5, Annex VIII, Regulation (EU) 2017/745

Notified Body name: for Class I not relevant.

Conformity assessment route: Annexes II & III, Rule 5, Regulation (EU) 2017/745.

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.

Signature:

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Dr. Oleg Mikhalev
General manager

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

Moscow, Russia
01.07.2024



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Annex to Declaration of Conformity

List of Products

Catalogue number	Product name
1.310	Saddle Metal Matrices
1.320	Saddle Metal Matrices
1.330	Saddle Metal Matrices. Universal Kit
1.198	Sectional Contoured Metal Matrices
1.298	Sectional Contoured Metal Matrices
1.398	Sectional Contoured Metal Matrices
1.498	Sectional Contoured Metal Matrices
1.338	Lug Matrices
1.348	Lug Matrices
1.368	Lug Matrices
1.870	Fixing Kit Delta
1.370	Do-All Proxicut System
1.379	Arc Proxicut System
1.965	Contact and Shape Former

Dr. Oleg Mikhalev,
General manager
01.07.2024