



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: 463003499DENREC6F

Name of the Device (s): **Hand-Held Dental Retractors**
(Annex specifying List of Products is an integral part of this Declaration)

Product code: 13380, Hand-Held Dental Retractor

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.

Signature: 
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Dr. Oleg Mikhalev
General manager

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

Moscow, Russia
03.08.2022



Annex to Declaration of Conformity

List of Products

Catalogue number	Product name
Dental Retractors	
1.011	Cheek Retractor
1.012	Cheek Retractor
1.013	Lip & Cheek Retractor
1.017	Cheek & Tongue Retractor
1.016S	Gingival Cord Packer, Small
1.016R	Gingival Cord Packer, Medium
1.019	Cheek & Tongue Retractor
1.117	Cheek & Tongue Retractor with Handle
1.119	Cheek & Tongue Retractor with Handle
Cotton roll holder	
1.010	Cotton Roll Holder

Dr. Oleg Mikhalev,
General manager
August 03, 2022