



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: 463003499RETRACD3

Name of the Device (s): **Hand-held dental retractors**
(Annex specifying List of Products is an integral part of this Declaration)

Product code: GMDN 13380, Hand-Held Dental Retractor

Classification: Class I

Notified Body name: for Class I not relevant.

Conformity assessment route: TOR VM uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:
Class I: EC conformity declaration according to Annex IV, Rule 5 and
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 10993-12:2012, EN ISO 10993-18:2009, EN 62366-1:2008, BS EN ISO 15223-1:2016

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) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Dr. Oleg Mikhalev
General manager



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

Moscow, Russia
27.12.2021



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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
December 27, 2021

