



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, 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.

Date of the first CE mark: 28.09.2018

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
Dental Retractors	
1.013	Retractor
1.016S	Gingival Cord Packer
1.019	Retractor
1.119	Retractor
Cotton roll holder	
1.010	Cotton Roll Holder

Dr. Oleg Mikhalev,
General manager
01.07.2024