

Dental Manufacturing Company Novatorov str., 7A bld.2, Moscow 119421, Russia e-mail: torvm77@gmail.com

Phone/fax: +7(495) 225 54 17 internet: www.torvm.ru

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.

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:

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

Dr. Oleg Mikhalev General manager

Moscow, Russia 10.01.2024



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Annex to Declaration of Conformity

List of Products

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

Dr. Oleg Mikhalev, General manager 10.01.2024



