



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: 463003499POLSTRGT

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

Product code: 35702, Dental Abrasive Strip, Single-Use

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



List of Products

Catalogue number	Product name
1.050	Strips for Gross Reduction (Coarse)
1.051	Strips for Contouring (Medium)
1.052	Strips for Polishing (Fine)
1.053	Strips. Universal Kit for Contouring
1.054	Strips. Universal Kit for Finishing
1.055	Polishing Strips. Universal Kit
1.384(1)	Proxicut Saw Blades
1.384(2)	Proxicut Saw Blades
1.385C(1)	Proxicut Diamond Strips, Coarse
1.385C(2)	Proxicut Diamond Strips, Coarse
1.385M(1)	Proxicut Diamond Strips, Medium
1.385M(2)	Proxicut Diamond Strips, Medium
1.385F(1)	Proxicut Diamond Strips, Fine
1.385F(2)	Proxicut Diamond Strips, Fine
1.370	Do-All Proxicut System
1.386	Metal Strips for Tartar Removal
1.150	Metal Diamond Strips (Coarse)
1.151	Metal Diamond Strips (Medium)
1.152	Metal Diamond Strips (Fine)
2.150	Metal Diamond Perforated Strips (Coarse)
2.151	Metal Diamond Perforated Strips (Medium)
2.152	Metal Diamond Perforated Strips (Fine)

Dr. Oleg Mikhalev,
General manager
August 03, 2022

CERTIFICATE



Medical Devices Quality Management System
CERTIFICATE NO: 31326801

TOR VM Ltd.

Novatorov, 7a, bld.2, Moscow, 119421, Russia

EN ISO 13485:2016

**Design, Manufacturing and Sales of Dental Polishing Discs and
Mandrels, Dental Matrices, Dental Wedges, Dental Strips, Dental
Rubber Dam Clamps and Related Instruments**

Approves that the Medical Devices Quality Management System implemented for above scope.

First Issue Date	25.09.2013
Issue Date	09.09.2022
Expiry Date	08.09.2025
Revision Date/No	09.09.2022 / 4



Deputy General Manager

The certificate inquiry is made by reading the QR codes by mobile devices, providing necessary information on <http://public.szutest.com.tr> or by using BDS No on <https://tdbs.turkak.org.tr>.