



Declaration of Conformity

Manufacturer: **TOR VM Ltd.**
SRN:
Address: Novatorov str., 7A, bld.2, room 44B, Moscow 119421
Manufacturing site: Kulibina, 15c, Voronezh, 394029
Country: Russia
Telephone No. +7 495 2255417

EC representative: Mr. Gregor Kostunov
SRN: DE-AR-000006585
Address: Untere Seegasse 54, DE-69124, Heidelberg
Country: Germany
Telephone: +49 (17) 626 400 019

Product ***Polishing Strips***
(Annex specifying List of Products is an integral part of this Declaration)

The undersigned hereby declares, on behalf of the TOR VM, Novatorov str., 7A, bld.2, room 44B, Moscow 119421, Russia that the above-referenced product, to which this declaration relates, is in conformity with the provisions of:

Regulation (EU) 2017/745 (Class I, Rule 5), Annex IV,
Assessment procedure according to Annex VIII, Rule 5, Regulation (EU) 2017/745,
and
EN 1041:2008, EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN 1639:2009, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 10993-12:2012, EN ISO 10993-18:2020, EN 62366-1:2015, EN 980:2008, BS EN ISO 15223-1:2016.

The technical construction file required by Regulation (EU) 2017/745, is maintained at the corporate headquarters of **TOR VM Ltd.** Novatorov str., 7A, bld. 2, room 44B, Moscow, 119421, and its official EC representative **Mr. Gregor Kostunov**, Address: Untere Seegasse 54, DE-69124 Heidelberg, Germany.

Notified Body for Class I not relevant.

GMDN code 35702, Dental Abrasive Strip, Single-Use

Date of the first CE mark: 10.08.2005
Valid: unlimited
Place of issue: Moscow, Russia
Date of issue: 26.05.2021


Dr. Oleg Mikhalev
General manager





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
May 26, 2021

