

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to Annex IX-Chapters I and III of the Regulation (EU) 2017/745 on
Medical Devices

Certificate No.: 2975-MED-2610601

Manufacturer: TOR VM Ltd.
Novatorov street, 7A, bld.2, room 44B, 119421 Moscow, Russia

Manufacturer's SRN: RU-MF-000016957

Authorized Representative: Gregor Kostunov
Untere Seegasse 54, DE-69124 Heidelberg, Germany
SRN DE-AR-000006585

Device Information: See Section 2

Report No.: MD0015-P001-R01

Specific Conditions or Limitations: N/A

Revision History: See Section 3

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality management system according to Annex IX Chapters I and III of the Regulation (EU) 2017/745 on medical devices. This quality system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex IX Chapter I Section 3 of the Regulation and unannounced site audits.

The Report(s) stated above summarize the conformity assessment results and include references to the relevant CS, harmonized standards, sampled/reviewed technical documentation, and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the device(s).

For placing on the market class III devices and class IIb devices referred to in the second subparagraph of Article 52(4) covered by this certificate, an EU Technical Documentation Assessment certificate according to Annex IX Chapter II is required.

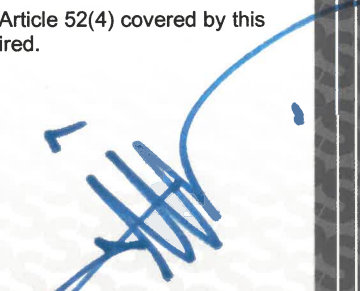
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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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www.zlg.de
BS-MDR-089




Mehmet İŞIKLAR
General Manager

This certificate can be validated by scanning the QR code or entering necessary information at <https://public.szutest-germany.de/>

1 / 2

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Section 2 – Device Information

No	Device(s) / Device Group(s)	Model(s)	Basic UDI-DI	Risk Class
1	Dental Polishing Discs and Mandrels	Disc Models: Discs of Coarse, Medium, Fine and Superfine Grades Mandrel Models: Mandrels of RA and HP Types	463003499DSCMND8Y	Ila

Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	16-04-2026	Initial Certification.