

MANAGEMENT SYSTEMS CERTIFICATION BODY «Elmas» LLC

office 4B17, 11, Zolotaya st., Moscow, 105094, Russia Accreditation certificate № POCC RU.0001.13ΦK14 issued by the Federal accreditation service

CERTIFICATE OF CONFORMITY

Edition 4.QMS has been certified since July 2012

is given to TOR VM Ltd
7a, bld. 2, apt. 44b, Novatorov str., Moscow, 119421, Russia, including the production site specified in the Annex

THIS CERTIFICATE CERTIFIES THAT:

Quality Management System as applied to design, development, production and delivery of Dental Polishing Discs and Mandrels, Dental Matrices, Dental Wedges, Dental Strips, Dental Rubber Dam Clamps, Dental Hand Instruments

COMPLIES WITH THE REQUIREMENTS OF GOST ISO 13485-2017 (ISO 13485:2016)

(Annex specifying the scope of QMS certification is an integral part of this certificate)

Registration RU CMS-RU.ΦK14.00328

Date of registration 2022, July 05

Deputy Head of Managementas Systems Certification Body

Audit team leader

It is valid until 2024, July, 13

A.B. Luchenko

T.V. Fadeeva

Annex

it is an integral part of the certificate No

RU CMS-RU.ΦK14.00328

Certification scope

Quality Management System of the TOR VM Ltd

1. Product:

Dental Polishing Discs and Mandrels, Dental Matrices, Dental Wedges, Dental Strips, Dental Rubber Dam Clamps, Dental Hand Instruments

- 2. Product Realization in conformity with GOST ISO 13485-2017:
- 7.1 Planning of Product Realization
- 7.2 Customer Related Processes
- 7.3 Design and Development
- 7.4 Purchasing
- 7.5 Production and Service Provision excluding installation works (7.5.3), Servicing (7.5.4), excluding special requirements for sterile medical device (7.5.5), validation of sterilization processes and sterility barrier systems (7.5.7) implantable medical devices (7.5.9.2), Customer Property (7.5.10)
- 7.6 Control of Monitoring and Measuring Devices
- 3. Address of the facility:

15c, Kulibina str., Voronezh, 394029, Russia

Further clarifications regarding the Quality Management Certificate Scope may be obtained by applying to the TOR VM Ltd

Deputy Head of Management

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Systems Certification Водусертификатов

Audit team leader

A.B. Luchenko

T.V. Fadeeva