

# MANAGEMENT SYSTEMS CERTIFICATION BODY «Elmas» LLC

office 4B17, 11, Zolotava st., Moscow, 105094, Russia Accreditation certificate № POCC RU.0001.13ФK14 issued by the Federal accreditation service

# CERTIFICATE OF CONFORMITY

Edition 5.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)

сертификатов

Registration RU CMS-RU.ΦK14.00395

Date of registration 2024, July, 12

It is valid until 2027, July, 12

Deputy Head of Management Menea

Systems Certification Body

A.B. Luchenko

Audit team leader

T.V. Fadeeva

### Annex

it is an integral part of the certificate **N**<sub>2</sub>

RU CMS-RU ΦK14.00395

## 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 <u>excluding installation works (7.5.3)</u>, <u>Servicing (7.5.4)</u>, <u>excluding special requirements for sterile medical device (7.5.5)</u>, <u>implantable medical devices (7.5.9.2)</u>, <u>Customer Property (7.5.10)</u>
- 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

сертификатов

Deputy Head of Management Systems Certification Body

Audit team leader

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A.B. Luchenko

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T.V. Fadeeva