



BSCIC

Certificate

M E D I C A L D E V I C E -
Q U A L I T Y M A N A G E M E N T S Y S T E M
This is to certify that:

**JSC "YELATMA INSTRUMENT MAKING
ENTERPRISE" (ELAMED)**

**391351, RUSSIAN FEDERATION, RYAZAN REGION, KASIMOVSKY
DISTRICT, YELATMA, ST. YANINA, 25**

Hereby granted the Certificate Number:

BN22189/21102

Rev.00

Subsequent to the **Assessment** of the organization, it has been found to be operating a Medical Device-
Quality Management System which complies with the requirements of

ISO 13485:2016

For the following scope:

**Design, Manufacture and Distribution of Medical IVD Containers, Disinfection and
Pre-Cleaning Devices, Furniture and Electro-Medical Devices for Therapy and Diagnostics**

**Technical Area: General Non-Active, Non-Implantable Medical Devices, Non-Active Instruments, A.1.1.6,
Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing, A.1.1.8, Non-Active Medical Devices Other than
Specified Above, A.1.1.21.**

**General Active Medical Devices, Active Ophthalmologic Devices, A.1.2.5, Active Devices for Disinfection and
Sterilization, A.1.2.7, Active Rehabilitation Devices and Active Prostheses, A.1.2.8, In Vitro Diagnostic Medical
Devices (IVD), IVD Medical Devices other than Specified Above, A.1.4.9.**

For
BSCIC CERTIFICATIONS PVT.LTD.

Sanjay Seth
Managing Director

Originally Registered: **16-Jun-2023**
Issue Date: **16-Jun-2023**
Expiry Date: **15-Jun-2026**

1st Surveillance Due on: **15-Jun-2024**

2nd Surveillance Due on: **15-Jun-2025**

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be
Suspended/Withdrawn).

Please Re-validate this certificate's status at www.bsc-icc.com at REGISTRATION STATUS.

This Certificate of Registration is granted subject to relevant provisions of the BSCIC Certifications PVT. LTD. Contract Terms & Scheme for
Registration Form B018 (Latest Version). Please see B018 at our website www.bsc-icc.com.

The certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request.

BSCIC Headquarters: &work, 1st Floor, 5B/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India.

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Certificate

Appendix-1

This Appendix is referred to Page 1 of BN22189//21102

MEDICAL DEVICE - QUALITY MANAGEMENT SYSTEM

This is to certify that:

**JSC "YELATMA INSTRUMENT MAKING
ENTERPRISE" (ELAMED)**

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| SITE ADDRESS | SCOPE |
|--|---|
| 391351, RUSSIAN FEDERATION, RYAZAN REGION, KASIMOVSKY DISTRICT, YELATMA, ST. YANINA, 25 | Design, Manufacture and Distribution of Medical IVD Containers, Disinfection and Pre-Cleaning Devices, Furniture and Electro-Medical Devices for Therapy and Diagnostics Technical Area: General Non-Active, Non-Implantable Medical Devices, Non-Active Instruments, A.1.1.6, Non-Active Medical Devices for Disinfecting, Cleaning, Rinsing, A.1.1.8, Non-Active Medical Devices Other than Specified Above, A.1.1.21. General Active Medical Devices, Active Ophthalmologic Devices, A.1.2.5, Active Devices for Disinfection and Sterilization, A.1.2.7, Active Rehabilitation Devices and Active Prostheses, A.1.2.8, In Vitro Diagnostic Medical Devices (IVD), IVD Medical Devices other than Specified Above, A.1.4.9. |
| 391351, RUSSIAN FEDERATION, RYAZAN REGION, KASIMOVSKY DISTRICT, YELATMA, ST. POLEVAYA, 54 | |
| 391351, RUSSIAN FEDERATION, RYAZAN REGION, KASIMOVSKY DISTRICT, YELATMA, ST. LENINA, 68 | |
| 602101, RUSSIAN FEDERATION, VLADIMIR REGION, MELENKOVSKY DISTRICT, MELENKI, ST. ZHELEZNODOROGNAYA, 3 | |
| 390000, RUSSIAN FEDERATION, RYAZAN, ST. TRUBEZHNAJA, 16 | |
| 390029, RUSSIAN FEDERATION, RYAZAN, ST. VISOKOVOLTNAYA, 48 | |

For
BSCIC CERTIFICATIONS PVT.LTD.



Sanjay Seth
Managing Director

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