



# BSCIC

# Certificate

MEDICAL DEVICE -  
QUALITY MANAGEMENT SYSTEM

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** 1st Surveillance Due on: **15-Jun-2024**  
Issue Date: **16-Jun-2023** 2nd Surveillance Due on: **15-Jun-2025**  
Expiry Date: **15-Jun-2026**

(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Suspended/Withdrawn).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](http://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](http://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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QM 030



# BSCIC

# Certificate

Appendix-1

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

**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**

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ENTERPRISE" (ELAMED)**

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SITE ADDRESS	SCOPE
391351, RUSSIAN FEDERATION, RYAZAN REGION, KASIMOVSKY DISTRICT, YELATMA, ST. YANINA, 25	<b>Design, Manufacture and Distribution of Medical IVD Containers, Disinfection and Pre-Cleaning Devices, Furniture and Electro-Medical Devices for Therapy and Diagnostics</b> 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. TRUBEZHAYAYA, 16	
390029, RUSSIAN FEDERATION, RYAZAN, ST. VISOKOVOLTNAYA, 48	

For  
**BSCIC CERTIFICATIONS PVT.LTD.**

Sanjay Seth  
Managing Director

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