



# CERTIFICATE



This is to certify that the company

## MESI, Development of medical devices, Ltd.

Stegne 11A  
1000 Ljubljana  
Slovenia

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design and Development, Manufacturing, Distribution and Servicing of active diagnostic Systems for physiological Parameters.

**-AUS (a), BRA, JPN, CND, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	546161 MDSAP16
Certificate unique ID	1000320779
Effective date	2026-05-27
Expiry date	2027-07-04
Frankfurt am Main	2026-05-27



## DQS Medizinprodukte GmbH

Sven Hoffmann  
Managing Director





**Annex to certificate**  
**Certificate registration No.: 546161 MDSAP16**  
**Certificate unique ID: 1000320779**  
**Effective date: 2026-05-27**

## **MESI, Development of medical devices, Ltd.**

Stegne 11A  
1000 Ljubljana  
Slovenia

### **Audited site**

**546161**  
**MESI, Development of medical devices, Ltd.**  
Stegne 11A  
1000 Ljubljana  
Slovenia

### **REPs FEI No.: site scope and country-specific requirements**

Design and Development, Manufacturing,  
Distribution and Servicing of active diagnostic  
Systems for physiological Parameters.  
**-AUS (a), BRA, JPN, CND, USA (a,b,c,d)**  
**REPs FEI No.: F005368**



**Annex to certificate**  
**Certificate registration No.: 546161 MDSAP16**  
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### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821