

# EU Quality Management System Certificate

Certificate no.  
7176GB448250703

Final Assessment Report no.  
7176AU13F

Effective date  
2025-07-03

Expiry date  
2030-03-23

This is to certify that the quality system of

**DAS Medical International, SRL**

Industrial Free Zone II, 22000 La Romana, Dominican Republic

SRN: DO-MF-000034519

For design, production, and final product inspection/testing of  
**Medical devices/groups of medical devices listed on the following pages**

Has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,  
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date  
Hamburg, 2025-07-03

For the issuing office  
DNV MEDCERT GmbH – Notified Body 0482  
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-096

The certificate is only valid when provided entirely with  
all of its pages. To verify the validity of this certificate,  
contact Medcert-Info@dnv.com

  
Annika Chm  
Certification Body Operations



**DNV**

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### Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

### Sites covered by this certificate

DAS Medical International, SRL, Industrial Free Zone II, 22000 La Romana, Dominican Republic

### Authorised representative

Sander/mdi Europa GmbH, Langenhagener Straße 71, 30855 Langenhagen, Germany SRN: DE-AR-000006218





**DNV**

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## Products covered by this certificate

### Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of medical devices
MDN 1214	Is	General non-active non-implantable devices used in health care and other non-active non implantable devices

