EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
4322GB448250120	4322AU18F	2025-01-20	2028-07-17

This is to certify that the quality system of

Medistri SA

Rte de L'Industrie 96, 1564, Domdidier, Switzerland

SRN: CH-PR-000039675

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, 2025-01-20

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

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

Marcus Harder
Certification Body

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

Certificate no.: 4322GB448250120
Place and date: Hamburg, 2025-01-20

Preceding certificate

Certificate no.	Issue date	Identification of changes
4322GB448240607	2024-06-07	WO-012340: New Site in Hungary - EtO sterilization

Sites covered by this certificate

Medistri SA, Rte de L'Industrie 96, 1564 Domdidier, Switzerland

Medistri Kft, Kamilla Utca 18, 8000 Székesfehérvár, Hungary

Authorised representative

International Associates Auditing & Certification Limited, The Black Church, St Mary's Place, D07 P4AX Dublin, Ireland
SRN: IE-AR-000002248

Certificate no.: 4322GB448250120
Place and date: Hamburg, 2025-01-20

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
MDS 1011	N/A	Devices in systems or procedure packs Sterile system and procedure packs according to Article 22 (3)