

EU Quality Management System Certificate

Certificate no. 4322GB448240607 Final Assessment Report no. 4322AU17F

Effective date 2024-06-07

Expiry date

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, 2024-06-07

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



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

Director Certification Bod

For the issuing office

DNV MEDCERT GmbH - Notified Body 0482 Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge



Certificate no.: 4322GB448240607 Place and date: Hamburg, 2024-06-07

Sites covered by this certificate

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

Authorised representative

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





Certificate no.: 4322GB448240607 Place and date: Hamburg, 2024-06-07

Products covered by this certificate

Category MDS 1011 Class N/A Medical devices/groups of medical devices

Devices in systems or procedure packs.

Sterile system and procedure packs according to Article 22 (3)

