

MANAGEMENT SYSTEM CERTIFICATE

Certificate no
4322GB452260115

Final assessment report no.
4322AU20F

Effective date
2026-01-15

Expiry date
2026-07-17

This is to certify that

Medistri SA

Rte de L'Industrie 96, 1564 Domdidier, Switzerland

has introduced, applies and maintains a management system at the sites listed on the following page(s).

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016 + AC:2018 + A11:2021

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2026-01-15

For the issuing office
DNV MEDCERT GmbH
Brooktorkai 18, 20457 Hamburg, Germany



Marcus Harder
Certification Body Operations

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.: 4322GB452260115
Place and date: Hamburg, 2026-01-15

Activities and products/services covered by this certificate

Manufacturing and distribution of

- Procedure packs

Provision of services for

- Customer-specific cleaning processes for the removal of processing residues from medical devices
- Sterilization of medical devices on the basis of EN ISO 11135:2014 + A1:2019
- Sterilization of medical devices on the basis of EN ISO 17665:2024

Sites covered by this certificate and associated (partial) scopes

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

Manufacturing and distribution of

- Procedure packs

Provision of services for

- Customer-specific cleaning processes for the removal of processing residues from medical devices
- Sterilization of medical devices on the basis of EN ISO 11135:2014 + A1:2019
- Sterilization of medical devices on the basis of EN ISO 17665:2024

Medistri Kft, Kamilla Utca 18, 8000 Székesfehérvár, Hungary

Provision of services for

- Sterilization of medical devices on the basis of EN ISO 11135:2014 + A1:2019