

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7331GB452250327A

Final assessment report no.
7331AU10F

Effective date
2025-03-27

Expiry date
2027-01-20

This is to certify that

MEDTRON AG

Hauptstraße 255, 66128 Saarbrücken, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

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, 2025-03-27

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

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 Chill
Certification Body

Activities and products/services covered by this certificate

Design and development, manufacturing, service, and distribution of

- Contrast media injectors
- Injectors for administration of fluids for therapeutic purposes
- Interfaces to radiological systems
- Remote controls
- Syringes for contrast media injectors
- Tube systems for contrast media injectors
- Application-sets for contrast media injectors
- Tube systems for administration of fluids for therapeutic purposes
- Syringes for administration of fluids for therapeutic purposes



Sites covered by this certificate and associated (partial) scopes

MEDTRON AG, Hauptstraße 255, 66128 Saarbrücken, Germany

Oversight on all matters related to the management process

MEDTRON AG, Nell-Breuning-Allee 6, 66115 Saarbrücken, Germany

Design and development of

- Contrast media injectors
- Injectors for administration of fluids for therapeutic purposes
- Interfaces to radiological systems
- Remote controls
- Syringes for contrast media injectors
- Tube systems for contrast media injectors
- Application-sets for contrast media injectors
- Tube systems for administration of fluids for therapeutic purposes
- Syringes for administration of fluids for therapeutic purposes

MEDTRON AG, Kreisstraße 152, 66128 Saarbrücken, Germany

Manufacturing, and servicing of

- Contrast media injectors
- Injectors for administration of fluids for therapeutic purposes
- Interfaces to radiological systems
- Remote controls

Distribution of

- Contrast media injectors
- Injectors for administration of fluids for therapeutic purposes
- Interfaces to radiological systems
- Remote controls
- Syringes for contrast media injectors
- Tube systems for contrast media injectors
- Application-sets for contrast media injectors
- Tube systems for administration of fluids for therapeutic purposes
- Syringes for administration of fluids for therapeutic purposes

MEDTRON AG, Gusenburger Straße 4, 54411 Hermeskeil, Germany

Manufacturing, and servicing of

- Syringes for contrast media injectors
- Tube systems for contrast media injectors
- Application-sets for contrast media injectors
- Tube systems for administration of fluids for therapeutic purposes
- Syringes for administration of fluids for therapeutic purposes