



MANAGEMENT SYSTEM CERTIFICATE

Certificate no
7331GB452260318

Final assessment report no.
7331AU10F

Effective date
2026-03-18

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 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, 2026-03-18

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



DAkkS

Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00


Annika Chill
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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.820115MS EN Rev 4 2026.03.13

CERTIFICATION BODY: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



Certificate no.: 7331GB452260318
Place and date: Hamburg, 2026-03-18

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
- Infusion pumps





Certificate no.: 7331GB452260318
Place and date: Hamburg, 2026-03-18

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
- Infusion pumps

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
- Infusion pumps

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
- Infusion pumps

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