

# 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



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





**DNV**

Certificate no.: [7331GB452250327A](#)  
Place and date: [Hamburg, 2025-03-27](#)

## 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