



# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
7331GB448260318

Final Assessment Report no.  
7331AU10F

Effective date  
2026-03-18

Expiry date  
2029-01-20

This is to certify that the quality system of

**MEDTRON AG**

Hauptstraße 255, 66128 Saarbrücken, Germany

SRN: DE-MF-000005188

For design & development, manufacturing and final product inspection/testing of  
**Medical devices/groups of medical devices at locations as 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, 2026-03-18

For the issuing office  
DNV MEDCERT GmbH – Notified Body 0482  
Brooktorkai 18, 20457 Hamburg, Germany



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
BS-MDR-096

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](mailto:medcert-info@dnv.com)

  
Anika Chill  
Certification Body Operations



Certificate no.: [7331GB448260318](#)  
Place and date: [Hamburg, 2026-03-18](#)

### Sites covered by this certificate

MEDTRON AG, Hauptstraße 255, 66128 Saarbrücken, Germany  
MEDTRON AG, Nell-Breuning-Allee 6, 66115 Saarbrücken, Germany  
MEDTRON AG, Kreisstraße 152, 66128 Saarbrücken, Germany  
MEDTRON AG, Gusenburger Straße 4, 54411 Hermeskeil, Germany

### Preceding certificate

<a href="#">Certificate no.</a>	<a href="#">Issue date</a>	<a href="#">Identification of changes</a>
7331GB448250729	2025-07-29	Addition in class IIb of MDA 0318 EMDN Z110390, MDA 0306 EMDN Z120303, MDA 0306 EMDN Z110590 and MDA 0306 EMDN Z110390



## Products covered by this certificate

### Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1202	A0201	SINGLE-USE SYRINGES
MDN 1202	A0202	REUSABLE SYRINGES
MDN 1202	A0302	EXTENSION LINES
MDN 1202	A0304	ADMINISTRATION KITS
MDN 1202	A0399	TUBULAR DEVICES - OTHER
MDN 1202	A0799	ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS – OTHER

### Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0318	Z110390	VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES

#### Intended purpose

The Interface Accutron HP is used exclusively to enable a communication link between the Injector Accutron HP and an angiography system. The scope of the communication can range from the exchange of status information between the devices to the control of the injector by the angiography system  
The Interface Accutron HP-D is used exclusively to enable a communication link between the injector Accutron HP-D and an angiography system. The scope of the communication can range from the exchange of status information between the devices to the control of the injector by the angiography system

### Class IIb active to administer medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	Z110390	VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES

#### Intended purpose

The injector Accutron CT-D is used for the controlled injection of contrast medium and physiological saline solution during interventional and diagnostic procedures in combination with X-ray imaging procedures such as computed tomography and X-ray mammography.  
The injector Accutron HP is used for the injection of contrast medium during interventional and diagnostic procedures in combination with X-ray imaging procedures  
The injector Accutron HP-D is used for the controlled injection of contrast medium and physiological saline solution during interventional and diagnostic procedures in combination with X-ray imaging procedures.  
The injector Accutron CT is used for the injection of contrast medium during interventional and diagnostic procedures in combination with X-ray imaging procedures such as computed tomography and X-ray mammography

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	Z120303	INFUSION INSTRUMENTS

#### Intended purpose

Syriflow MR is a non-magnetic infusion pump which can be used by qualified medical personnel when specific fluids must be administered to a patient. The medical indication includes, among other things, intensive care, anesthesia and neonatal and pediatric applications

Category	EMDN code	Medical devices/groups of medical devices
MDN 0306	Z110590	VARIOUS MAGNETIC RESONANCE IMAGING (MRI) INSTRUMENTS

#### Intended purpose

The injector Accutron MR is used for the controlled injection of contrast medium and physiological saline solution during interventional and diagnostic procedures in magnetic resonance imaging.  
The injector Accutron MR3 is used for the controlled injection of contrast medium and physiological saline solution during interventional and diagnostic procedures in magnetic resonance imaging.  
The integrated infusion pump is used for the administration of fluids for diagnostic purposes under constant monitoring by the user