

Certificate

The certification body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH Pilatuspool 2 — 20355 Hamburg — Germany

herewith certifies that the company

MEDTRON AG Hauptstraße 255 66128 Saarbrücken Germany

with locations listed in the appendix

has introduced, applies and maintains a quality management system in the area of:

Design and development, manufacture, final inspection, service and distribution of products as listed in the appendix

The conformity of this quality management system to the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date:

2020-07-09

Expiry date:

2022-01-20

Report No.:

7331PS05F

Procedure No.:

QS - 7331

Certificate No.:

7331GB445200709

Hamburg, 2020-07-09

MEDCERT Certification Body (Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de.

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Appendix of certificate

Procedure No.:

QS - 7331

Certificate No.:

7331GB445200709

List of locations included in the scope of certificate

MEDTRON AG Hauptstraße 255 66128 Saarbrücken Germany

MEDTRON AG Kreisstraße 152 66128 Saarbrücken Germany

MEDTRON AG Nell-Breuning-Allee 6 66115 Saarbrücken Germany

MEDTRON AG Gusenburger Straße 4 54411 Hermeskeil Germany

- End of list -

This appendix is integral part of the above-referenced certificate. The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de.

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Appendix of certificate

Procedure No.:

QS - 7331

Certificate No.:

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List of products included in the scope of certificate

- 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

- End of list -

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