EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI, Part A

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Fuhrmann GmbH
Bövingen 139
53804 Much
Germany

has established, documented and implemented a quality assurance system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex XI, Part A. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex XI,7.The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and Class IIb implantable devices an additional EU type examination certificate according to Annex X is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000006652; DE-PR-000019607
Authorised Representative:	N/A
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--
List of Products, Risk Classification and Details:	see section 2
Certificate history:	see section 3

Reg.-No.: 44 910 221046
Certification decision report No.: 3536 4103

Edition:	3
Issue date:	2024-06-26
First issued:	2024-05-24
Valid until:	2029-05-23

Essen, 2024-06-26 B. Hoy

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
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tuev-nord-cert.de
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex XI, Part A

Reg. No. 44 910 22 1046 Section 2, List of Products

Class IIa

Product name	Category of device (MDN)	Technical documentation assessment report number
Pointed swabs with x-ray / Spitztupfer mit Röntgenkontrast	MDN 1204	3533 9838
Gauze swabs with x-ray / Mullkompressen mit Röntgenkontrast		
Gauze balls with x-ray / Schlinggazetupfer mit Röntgenkontrast		
Preparation pads with x-ray / Präpariertupfer mit Röntgenkontrast		
Lap sponges / Bauchtücher		
Intestinal bags, Rolled edge compresses / Intestinalbeutel, Rollrandkompressen		
Cotton balls, Gynecological tampons / Wattebälle, Gynäkologische Tampons		
Gauze tamponades / Tamponaden Verbandmull		

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Product name	Category of device (MDN)	Technical documentation assessment report number
Single-use scissors / Einmal-Scheren, sonstige und Dissektion Single-use umbilical cord scissors / Einmal-Nabelschnurschere Single-use episiotomy scissors / Einmal-Episiotomischere Single-use forceps / Einmal-Pinzetten Single-use forceps / Einmal-Klemmen Single-use needle holder / Einmal-Nadelhalter Single-use dressing forceps / Einmal-Kornzangen Single-use magill forceps / Einmal-Magillzangen Single-use curettes / Einmal-Küretten Single-use retractors / Einmal-Wundhaken	MDN 1208	3533 9835

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EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex XI, Part A

Class I, sterile

Product name	Category of device (MDN)	Technical documentation assessment report number
Pointed swabs without x-ray / Spitztupfer ohne Röntgenkontrast Gauze swabs without x-ray / Mullkompressen ohne Röntgenkontrast Gauze, Non-woven balls without x-ray / Tupfer ohne Röntgenkontrast Non-woven swabs / Vlieskompressen Slit compresses / Schlitzkompressen Absorbent pads / Saugkompressen Cellulose swabs , Cellulose wipes / Zellstoffprodukte Cotton swabs / Wattestäbchen Cotton products / Watteprodukte Bandages, Tubular bandages / Binden und Schlauchverbände Nasopharyngeal tamponades / Nasen-Rachen-Tamponaden ENT protective bandages / HNO Schutzverbände Nasal tamponades/ Nasentamponaden Plastic bowls / Kunststoffschalen Single-use bandage scissors / Einmal-Verbandscheren Single-use suture scissors / Einmal-Fadenziehschere Single-use tubing clamp / Einmal-Schlauchklemmen Single-use vaginal specula / Einmal-Vaginalspekula	MDS 1005, MDN 1204, MDN 1208, MDN 1214	3533 9831, 3533 9830

For class Is devices placed on the market in a sterile condition, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to the manufacture, securing and maintenance of sterile conditions.

EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI, Part A

Sterile procedure packs acc. Art. 22,3

Product name / Product group name	Category of device (MDS, MDN)	Technical documentation assessment report number
Sterile Procedure Packs acc. Art. 22, 3 of Regulation (EU) 2017/745 Sterile Behandlungseinheiten gem. Art. 22, 3 der Verordnung (EU) 2017/745	MDS 1005, MDN 1214	3533 9933, 3533 9936

For procedure packs placed on the market in a sterile condition acc. Art. 22,3, the involvement of the notified body in the conformity assessment procedure is limited to those aspects related to ensuring sterility until the sterile packaging is opened or damaged.

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EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex XI, Part A

Reg. No. 44 910 22 1046 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
01	2024-05-24	Initial certification	ZA 3536 4103
02	2024-05-28	Editorial Change	ZA 3536 4103
03	2024-06-26	Editorial Change	ZA 3536 4103

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