EU Quality Management System Certificate

We hereby certify the company

Serumwerk Bernburg AG
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Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-03-07	Registration No.	D1054400056
Valid until	2027-04-21	Report No.	P22-00047-225463

Stuttgart, 2024-03-07

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Ready-to-use clyster for enema - 1xklysma saline
(1 x 135 ml, 10 x 135 ml)

Intended purpose:
Ready-to-use enema for rapid defecation of the rectum

Risk class: III

Bicarbonate cartridges for hemodialysis
(650 g DiaCart OP/F/C,
650 g DiaCart CP,
720 g DiaCart OP/F/C,
720 g DiaCart CP,
750 g DiaCart OP/F/C,
750 g DiaCart CP,
760 g DiaCart OP/F/C)

Intended purpose:
To produce an alkaline bicarbonate haemodialysis concentrate for extracorporeal bicarbonate haemodialysis or bicarbonate haemodiafiltration

Risk class: IIb

0.9% NaCl Irrigation solution (250 ml, 500 ml, 1000 ml, 2000 ml PP-Bags)

Intended purpose:
Sterile, isotonic saline solution for rinsing purposes

Risk class: IIa

Balanced salt solution (BSS) - (500 ml PP-Bag, 500 ml PP-Bottle, 250 ml PP-Bottle, 500 ml Glass-Bottle, 20 ml PP-Bottle)

Intended purpose:
Sterile rinsing solution for ophthalmic purposes

Risk class: IIa

Amnion Flush Solution (500 ml Glass-Bottle)

Intended purpose:
Sterile solution intended for the continuous transabdominal amnion irrigation after premature rupture of the amniotic sac

Risk class: IIb

Blood tubing systems for haemodialysis and sterile disposables

Intended purpose:
Connection of the dialyzer to the patient during dialysis treatment

Risk class: IIa

Degradable Starch Microspheres - FermoStar® and EmboLog®

Intended purpose:
Suspension for injection as an adjuvant in the intra-arterial treatment of liver tumors in combination with cytostatic agents to optimize intratumoral drug delivery

Risk class: III

Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate

D1054400049 (2023-02-02)
D1054400051 (2023-03-13)
D1054400052 (2023-09-04)

with the following changes to D1054400052:
Supplemented by the product: Amnion Flush Solution (500 ml Glass-Bottle) Sterile solution intended for the continuous transabdominal amnion irrigation after premature rupture of the amniotic sac