EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005169)

Serumwerk Bernburg AG

Hallesche Landstraße 105 b
06406 Bernburg
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils 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 consists of 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-09-04	Registration No.	D1054400052
Valid until:	2027-04-21	Evaluation Report No.	P23-00988-278114

Stuttgart, 2023-09-04

Head of Notified Body

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

Devices:

Product:
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

Product:
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

Product:
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

Product:
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

Product:
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

Product:
Blood tubing systems for haemodialysis and sterile disposables

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

Risk class: IIa

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 D1054400051 dated 13.03.2023 with the following changes:
Supplemented by the product groups:

- Blood tubing systems for haemodialysis and sterile disposables:
  Connection of the dialyzer to the patient during dialysis treatment
- Degradable Starch Microspheres - FermoStar® and EmboLog®:
  Suspension for injection as an adjuvant in the intra-arterial treatment of liver tumors in combination with cytostatic agents to optimize intratumoral drug delivery

Correction of wording (no trade name)
- „Balanced salt solution (BSS)“ instead of „BSS Eye-Lotion Balanced salt solution“