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 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 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-02-02	Registration No.	D1054400049
Valid until:	2027-04-21	Evaluation Report No.	P22-00760-236628

Stuttgart, 2023-02-02

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:
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
Basic-UDI-DI: 426020097CARTRIDGE2K

Product:
0,9% NaCl Rinsing solution

Intended purpose: Sterile, isotonic saline solution for rinsing purposes; 250ml, 500ml, 1000ml, 2000 ml PP-Pouches in Cardboard box

Risk class: IIa
Basic-UDI-DI: 426020097NACL43
