## Certificate

mdc medical device certification GmbH certifies that

## Serumwerk Bernburg AG Hallesche Landstraße 105 b 06406 Bernburg Germany

for the scope

design, manufacturing and distribution of degradable starch microspheres, non-sterile clyster for enema, Amnion Flush Solution, sterile eye rinsing solutions, sterile NaCl rinsing solutions, bicarbonate cartridges for hemodialysis, sterile blood tubing sets including accessories for hemodialysis and other sterile single-use products and manufacturing of solutions for hemodialysis, hemodiafiltration and hemofiltration

has introduced and applies a

## **Quality Management System**

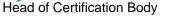
The mdc audit has proven that this quality management system meets all requirements of the following standard

## EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Valid from Valid until Registration no. Report no. Stuttgart 2022-12-04 2025-12-03 D1054400047 P22-00760-236616 2022-11-23







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