

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	2022-12-04
Valid until	2025-12-03
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Head of Certification Body

