# Certificate

#### mdc medical device certification GmbH

certifies that

### Serumwerk Bernburg Vertriebs GmbH Hallesche Landstraße 105 b 06406 Bernburg Germany

for the scope

development, manufacturing and distribution of sterile eye rinsing solutions, sterile NaCl rinsing solutions, bicarbonate cartridges for hemodialysis, sterile blood tube systems including accessories for hemodialysis and other sterile single-use products

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:2016 - ISO 13485:2016

 Valid from
 2019-12-15

 Valid until
 2022-12-14

 Registration no.
 D1082900025

 Report no.
 P19-01207-154700

 Stuttgart
 2019-12-15

**Head of Certification Body** 





Internet: http://www.mdc-ce.de