

# 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 and  
Amnion Flush Solution as well as manufacturing of sterile eye rinsing solutions,  
sterile NaCl rinsing solutions and hemodialysis, hemofiltration and  
hemodiafiltration solutions**

has introduced and applies a

## Quality Management System

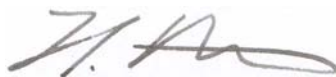
The mdc audit has proven that this quality management system  
meets all requirements of the following standard

### EN ISO 13485

Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2019-12-04
Valid until	2022-12-03
Registration no.	D1054400040
Report no.	P19-01201-154629
Stuttgart	2019-12-04



Head of Certification Body

