

Certificate

We hereby certify the company

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in 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

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-12-04
Valid until 2028-12-03

Registration No. D1054400062
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Stuttgart, 2025-12-01



Certification Body

