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 tubing sets 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:2018 + A11:2021 - ISO 13485:2016

Valid from Valid until Registration no. Report no. Stuttgart 2022-12-15 2025-12-14 D1082900029 P22-00759-236605 2022-09-21

Head of Certification Body





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