

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

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

for the scope

**sterile eye rinsing solutions
(PP bottles: 20 ml, 250 ml, 500 ml; glass bottles: 500 ml; bags: 500 ml)
sterile NaCl rinsing solutions
(bags: 500 ml, 1000 ml, 2000 ml, 5000 ml)
bicarbonate cartridges for haemodialysis, sterile blood tubing systems
including accessories for haemodialysis and other sterile single-use products**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-02-15
Valid until	2024-05-26
Registration no.	D1082900028
Report no.	P19-01841-166194
Stuttgart	2021-02-15

Head of Certification Body



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bei Arzneimitteln und
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