

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: 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 tube 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	2020-02-24
Valid until	2024-05-26
Registration no.	D1082900027
Report no.	P19-01839-166150
Stuttgart	2020-02-24



Head of Certification Body

