

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, sterile NaCl rinsing solutions,
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	2017-05-22
Valid until	2021-12-14
Registration no.	D1082900022
Report no.	P16-01540-97958
Stuttgart	2017-05-22



Head of Certification Body

