

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany**

for the scope

**Degradable Starch Microspheres
(Suspension for injection as an adjuvant in the intra-arterial treatment of
liver and lung tumors in combination with cytostatic agents) and
Amnion Flush Solution**

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	2019-12-04
Valid until	2024-05-26
Registration no.	D1054400038
Report no.	P19-01201-154634
Stuttgart	2019-12-04



Head of Certification Body

