EU Technical Documentation Assessment Certificate

We hereby certify that the company

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2026-04-01	Registration No.	D1054400063
Valid until	2027-04-21	Report No.	P24-01437-359318

Stuttgart, 2026-03-31

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-098

Devices:

Degradable Starch Microspheres (DSM)

- EmboLog® S; Art.No. 3324 / Typ 450mg / 7.5ml Amilomer and Art.No. 3037 / Typ 240mg / 4.0ml Amilomer
- FermoStar; Art.No. 3326 / Typ 450mg / 7.5ml Amilomer and Art.No. 3213 / Typ 240mg / 4.0ml Amilomer

Intended purpose: Suspension for injection as an adjuvant in the intra-arterial treatment of liver tumors in combination with cytostatic agents to optimize intratumoral drug delivery

Risk class: III
Basic UDI-DI: 426020097DSMC3

Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.

The certificate is based on the previous certificate

D1054400053 (2023-09-04)

with the following changes to D1054400053:
Supplemented by: FermoStar; Art.No. 3326 / Typ 450mg / 7.5ml Amilomer and Art.No. 3213 / Typ 240mg / 4.0ml Amilomer