EU Technical Documentation Assessment Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005169)

Serumwerk Bernburg AG

Hallesche Landstraße 105 b
06406 Bernburg
Germany

has submitted a technical documentation for the devices listed on the following pages in accordance with Annexes II and III of Regulation (EU) 2017/745, which fulfils 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.

The certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-09-04	Registration No.	D1054400054
Valid until:	2027-04-21	Evaluation Report No.	P21-00232-197843

Stuttgart, 2023-09-04

Head of Notified Body

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

Devices:

Product:
Degradable Starch Microspheres (Suspension for injection as an adjuvant in the intra-arterial treatment of liver tumors in combination with cytostatic agents) - 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.