

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-000004939)

MBP Medical Biomaterial Products GmbH

Lederstraße 7
19306 Neustadt-Glewe
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:

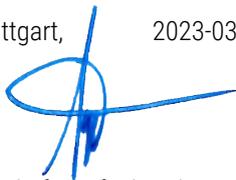
Annex IX - Chapter II (Assessment of the Technical Documentation)

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:	2023-03-14	Registration No.	D1417000039
Valid until:	2028-03-13	Evaluation Report No.	P22-00856-237839

Stuttgart, 2023-03-14



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:

MB-Collagen/ 0505C/ 5*5 cm

Intended purpose:

Wound dressing with an indication for the following conditions:

- Non-infected wounds with wound healing disorders.
- Wounds with secondary wound healing in the granulation phase
- Wounds in the epithelialization phase (e.g. leg ulcers, decubital ulcers, split-thickness skin graft wounds, burn wounds, secondary healing wounds)

Risk class: III

Basic-UDI-DI: 426023091001

Product: MB-Collagen/ 0510C/ 5*10 cm

Intended purpose:

Wound dressing with an indication for the following conditions:

- Non-infected wounds with wound healing disorders.
- Wounds with secondary wound healing in the granulation phase
- Wounds in the epithelialization phase (e.g. leg ulcers, decubital ulcers, split-thickness skin graft wounds, burn wounds, secondary healing wounds)

Risk class: III

Basic-UDI-DI: 426023091002

Product: MB-Collagen/ 1010C/ 10*10 cm

Intended purpose:

Wound dressing with an indication for the following conditions:

- Non-infected wounds with wound healing disorders.
- Wounds with secondary wound healing in the granulation phase
- Wounds in the epithelialization phase (e.g. leg ulcers, decubital ulcers, split-thickness skin graft wounds, burn wounds, secondary healing wounds)

Risk class: III

Basic-UDI-DI: 426023091003

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.