

# 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:

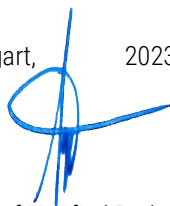
Annex IX - Chapter II (Assessment of the Technical Documentation)

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

The certificate consists of 4 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-08-11	Registration No.	D1417000045
Valid until:	2028-08-10	Evaluation Report No.	P23-00244-259652

Stuttgart, 2023-08-11



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:

Xenoderm / 0505X / 50\*50 mm / 10 pieces/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090301

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Product:

Xenoderm / 1010X / 100\*100 mm / 5 pieces/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090302

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Product:

Xenoderm / 1020X / 100\*200 mm / 5 pieces/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090303

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Product:

Xenoderm / 1030X / 100\*300 mm / 5 pieces/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090304

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Product:

Xenoderm / 1040X / 100\*400 mm / 5 pieces/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090305

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Product:

Xenoderm / Z0505X / 50\*50 mm / 1 piece/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090301

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Product:

Xenoderm / Z1010X / 100\*100 mm / 1 piece/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090302

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Product:

Xenoderm / Z1020X / 100\*200 mm / 1 piece/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090303

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Product:

Xenoderm / Z1030X / 100\*300 mm / 1 piece/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090304

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Product:

Xenoderm / Z1040X / 100\*400 mm / 1 piece/box

Intended purpose:

Xenoderm is used as a temporary skin replacement, to cover second and third degree skin loss due to burns and trauma, to cover chronic non-healing wounds such as venous, diabetic or pressure ulcers, to cover autologous grafts and to cover donor sites

Risk class: III

Basic-UDI-DI: 426023090305

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## 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.