

# 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:

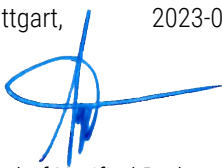
Annex IX - Chapter II (Assessment of the Technical Documentation)

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:	2023-03-14	Registration No.	D1417000041
Valid until:	2028-03-13	Evaluation Report No.	P22-01234-243896

Stuttgart, 2023-03-14



Head of Notified Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-098

## Devices:

Product:

Surgicoll, S0101K, 10\*10 mm

Intended purpose:

Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III

Basic-UDI-DI: 426023090901

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Product:

Surgicoll, S0505K, 50\*50 mm

Intended purpose:

Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III

Basic-UDI-DI: 426023090902

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Product:

Surgicoll, S0510K, 50\*100 mm

Intended purpose:

Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III

Basic-UDI-DI: 426023090903

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Product:

Surgicoll, S1010K, 100\*100 mm

Intended purpose:

Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III

Basic-UDI-DI: 426023090904

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Product:  
Hemocol, H0101K, 10\*10 mm

Intended purpose:  
Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III  
Basic-UDI-DI: 426023090905

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Product:  
Hemocol, H0505K, 50\*50 mm

Intended purpose:  
Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III  
Basic-UDI-DI: 426023090906

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Product:  
Hemocol, H0510K, 50\*100 mm

Intended purpose:  
Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III  
Basic-UDI-DI: 426023090907

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Product:  
Hemocol, H1010K, 100\*100 mm

Intended purpose:  
Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III  
Basic-UDI-DI: 426023090908

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Product:

Diacoll, D0202K, 20\*20 mm

Intended purpose:

Absorbable, local haemostyptic agent for single use. The product is indicated wherever capillary, venous, small arterial and diffuse seeping bleedings must be stopped, and where conventional means of hemorrhage control are either inadequate or technically difficult and time-consuming.

Risk class: III

Basic-UDI-DI: 426023090910

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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.