# EC Certificate

**mdc medical device certification GmbH**
Notified Body 0483
herewith certifies that

**botiss biomaterials GmbH**
**Hauptstraße 28**
**15806 Zossen**
**Germany**

for the scope

**bone graft materials, hemostyptica and resorbable and non-resorbable membranes, resorbable magnesium devices (see attachment)**

has introduced and applies a

## Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

## Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

| | |
|---|---|
| Valid from | 2021-03-02 |
| Valid until | 2024-05-26 |
| Registration no. | D1323300046 |
| Report no. | P20-01242-200112 |
| Stuttgart | 2021-03-02 |

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de ZLG-BS-246.10.06

mdc medical device certification GmbH
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Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

**Attachment of the certificate**

**No. D1323300046** Date 2021-03-02 

| Product category | Class |
|---|---|
| resorbable magnesium devices (NOVAMag) fixation screw and membrane | III |
| bone graft materials, hemostyptica and resorbable membranes | III |
| bone graft material (cerabone® and cerabone® plus) | III (TSE) |
| non-resorbable membrane (PTFE) | IIb |

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# Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | botiss biomaterials GmbH |
| Manufacturer address and contact details | Hauptstr. 28, 15806 Zossen, Germany<br>Tel./Phone: +49 33769 / 88 41 985<br>Fax: +49 33769 / 88 41 986 |
| Single Registration Number (SRN) (if available) | DE-MF-000010846 |

| | |
|---|---|
| Authorised Representative name (if applicable) | N/A |
| Authorised Representative address and contact details | N/A |
| Single Registration Number (SRN) (if available) | N/A |

| | |
|---|---|
| Notified body name (if applicable) | □ See attached schedule |
| Notified body number (if applicable) | □ See attached schedule |
| Directive Certificate number(s)<br>to which this confirmation is made (if applicable) | □ See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | □ See attached schedule |
| End date of extended validity/transition period | □ See attached schedule |

We, as the manufacturer declare under our sole responsibility:

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  *Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒ Expired/expires *after* 20 March 2023:

*Choose one applicable statement:*

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

*Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

botiss biomaterials GmbH

Zossen, 22.05.2024

K. Pratsch

D. Tadic

Katja Pratsch, Managing Director QM & RA
Email: Katja.Pratsch@botiss.com

Dr. Drazen Tadic, PRRC-QA/TD
Email: Drazen.Tadic@botiss.com

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**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

| **Identification of the device(s)**[3] (e.g., device name, family/group name device model or catalogue number) | **Directive Certificate number(s) to which this confirmation is made** (if applicable) | **Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) | **Notified Body name and number that issued the Directive Certificate** (if applicable) | **Notified Body name and number where the MDR application was lodged/contract signed** (if applicable) | **End date of extended validity / transition period** | **Substitute Device(s)** (if applicable) |
|---|---|---|---|---|---|---|
| **cerabone®**<br>REF:<br>1510<br>1511<br>1512<br>1515<br>1520<br>1521<br>1522<br>1525 | D1323300040<br>D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **cerabone® plus**<br>REF:<br>1810<br>1811<br>1820<br>1821 | D1323300040<br>D1323300046<br>D1323300047 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **collacone®**<br>REF:<br>511112 | D1323300028<br>D1323300046 | 2024-04-30<br>2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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IBAN: DE38100900002157239000
BIC: BEVODEBBXXX
Visa, MasterCard, PayPal

| | | | | | | |
|---|---|---|---|---|---|---|
| **collafleece®**<br>REF:<br>512212 | D1323300038<br>D1323300046 | 2024-04-30<br>2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **Jason® membrane**<br>REF:<br>681520<br>682030<br>683040 | D1323300033<br>D1323300046<br>D1323300052 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **maxresorb®**<br>REF:<br>20005<br>20010<br>20105<br>20120 | D1323300036<br>D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **collprotect® membrane**<br>REF:<br>601520<br>602030<br>603040 | D1323300029<br>D1323300041<br>D1323300046<br>D1323300053 | 2024-04-30<br>2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **mucoderm®**<br>REF:<br>701520<br>702030<br>703040<br>710210 | D1323300032<br>D1323300039<br>D1323300046<br>D1323300054 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **permamem®**<br>REF:<br>801520<br>802030<br>803040 | D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |

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| | | | | | | |
|---|---|---|---|---|---|---|
| **NOVAMag® membrane**<br>REF:<br>721520<br>722030<br>723040 | D1323300043<br>D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **NOVAMag® fixation screw**<br>REF:<br>74100402<br>74100404<br>74140701<br>74140901<br>74141101<br>74141301 | D1323300044<br>D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2027-12-31 | N/A |
| **NOVAMag® connector**<br>REF:<br>74000<br>74004<br>74008 | D1323300046 | 2024-05-26 | mdc medical device certification GmbH<br>0483 | mdc medical device certification GmbH<br>0483 | 2028-12-31 | N/A |

## Revision History

| Version | Effective Date | Reason for Change |
|---|---|---|
| 01 | 2024-01-22 | Initial |

| | | |
|---|---|---|
| 02 | 2024-04-25 | Decision, that we do not apply for conformity assessment according to Regulations (EU) 2017/745 for the following product variants:<br><br>mucoderm® REF:<br>701030, 702050, 703005, 702000, 710208<br><br>maxresorb® inject REF: 22005, 22010, 22025 |
| 03 | 2024-05-22 | Addition of MDD certificates for cerabone® plus, Jason membrane®, collprotect® membrane and mucoderm® |

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