botiss biomaterials

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 Tel./Phone: +49 33769 / 88 41 985 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) 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

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

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

Schedule of Devices

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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® REF: 1510 1511 1512 1515 1520 1521 1522 1525	D1323300040 D1323300046	2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 0483	2027-12-31	N/A
cerabone® plus REF: 1810 1811 1820 1821	D1323300040 D1323300046 D1323300047	2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 0483	2027-12-31	N/A
collacone® REF: 511112	D1323300028 D1323300046	2024-04-30 2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 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)

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

NOVAMag® membrane REF: 721520 722030 723040	D1323300043 D1323300046	2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 0483	2027-12-31	N/A
NOVAMag® fixation screw REF: 74100402 74100404 74140701 74140901 74141101 74141301	D1323300044 D1323300046	2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 0483	2027-12-31	N/A
NOVAMag® connector REF: 74000 74004 74008	D1323300046	2024-05-26	mdc medical device certification GmbH 0483	mdc medical device certification GmbH 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: mucoderm® REF: 701030, 702050, 703005, 702000, 710208 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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