

EC-DECLARATION OF CONFORMITY

According to annex II of the Council Directive 93/42/EEC concerning medical devices

We:

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen
Germany

herewith declare under our sole responsibility that the below mentioned product (sterile, class III, rule 8) meets the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer. The conformity assessment route follows Annex II.3 and II.4.

Object of Declaration: **NOVAMag® membrane**

Size	Content	REF
15 x 20 mm	1 membrane	721520
20 x 30 mm	1 membrane	722030
30 x 40 mm	1 membrane	723040

Notified Body:

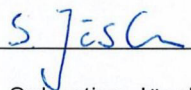
mdc medical device certification GmbH; Kriegerstraße 6, 70191 Stuttgart, Germany, CE 0483

EC Certificate Full Quality Assurance System No. D1323300046, valid until 2024-05-26

EC Design Examination Certificate No. D1323300043, valid until 2024-05-26

This Declaration of Conformity is valid until 2024-05-26.

Place, Date: Zossen, 2021-05-25


Dr. Sebastian Jäschke
(Lead RA Europe)




Dr. Drazen Tadic
(PRRC-QA/TD)

botiss biomaterials GmbH | Hauptstr. 28 | 15806 Zossen / Germany



First Amendment to EC-DECLARATION OF CONFORMITY for the medical device NOVAMag® membrane dated 2021-05-25

We:

botiss biomaterials GmbH

Hauptstraße 28

15806 Zossen

Germany

Herewith we declare under our sole responsibility that the following GMDN code has been assigned to the medical device NOVAMag® membrane

66715– Bioabsorbable-metal dental regeneration membrane

The previously assigned GMDN code was set obsolete.

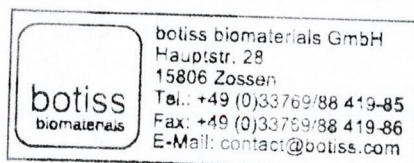
The other particulars on the declaration of conformity are not affected by this change.

Place, Date: Zossen, 11.01.2024

K. Pratsch

Katja Pratsch

(Lead RA Europe)



Dr. Drazen Tadic

Dr. Drazen Tadic

(PRRC-QA/TD)



botiss biomaterials GmbH | Hauptstr. 28 | 15806 Zossen / Germany

Second Amendment to EC-DECLARATION OF CONFORMITY for the medical device **NOVAMag® membrane** dated 2021-05-25

We:

botiss biomaterials GmbH

Hauptstraße 28

15806 Zossen

Germany

Herewith we declare that the shelf life of the **NOVAMag® membrane** is extended from one year to three years.

All necessary actions for the implementation of the three years shelf life have been done.

Safety and Performance of the **NOVAMag® membrane** are not affected.

The other particulars on the declaration of conformity are not affected by this change.

Place, Date: Zossen, 30.01.2024

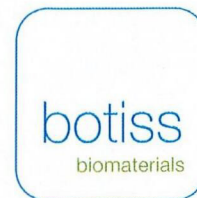
Katja Pratsch

(Lead RA Europe)



Dr. Drazen Tadic

(PRRC-QA/TD)



botiss biomaterials GmbH | Hauptstr. 28 | 15806 Zossen / Germany

Third Amendment to EC-DECLARATION OF CONFORMITY for the medical device **NOVAMag® membrane** dated 2021-05-25

We:

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen
Germany

herewith declare that in accordance with Regulation (EU) 2023/607 and paragraph 3 of article 120 of Regulation (EU) 2017/745 the medical device continues to comply with Directive 93/42/EEC under the conditions stated in the **attached Manufacturer's Declaration**.

The validity of the hereby amended Declaration of Conformity is therefore **extended until** 2027-12-31.

The declaration is valid for the following article REFs:

REF:	Name:
721520 722030 723040	NOVAMag® membrane

Place, Date: Zossen, 2024-01-30

Katja Pratsch
(Lead RA Europe)

Dr. Drazen Tadic
(PRRC-QA/TD)



botiss biomaterials GmbH | Hauptstr. 28 | 15806 Zossen / Germany

Fourth Amendment to EC-DECLARATION OF CONFORMITY for the medical device **NOVAMag® membrane** dated 2021-05-25

We:

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen
Germany

herewith declare under our sole responsibility that an additional product variant (Ref. 721020) of NOVAMag® membrane has been approved by the Notified Body mdc by issuing the supplementary certificate No. D1323300061. The validity of the supplementary certificate depends on the validity of the underlying EC Design Examination Certificate with the no. D1323300043.

Object of Declaration: **NOVAMag® membrane**

Product	Size	Content	REF
NOVAMag® membrane XS	10 x 20 mm	1 Membrane	721020

Place, Date: Zossen, 17.10.2024

K. Pratsch

Katja Pratsch
(Managing Director Quality Management
& Regulatory Affairs)

Dr. Drazen Tadic

Dr. Drazen Tadic
(PRRC-QA/TD)

Fifth Amendment to EC-DECLARATION OF CONFORMITY for the medical device **NOVAMag® membrane** dated 2021-05-25

We:

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen
Germany

herewith declare under our sole responsibility that an additional product variant (Ref. 721212) of NOVAMag® SHIELD has been approved by the Notified Body mdc. The newly introduced size is covered under certificate No. D1323300043.

Object of Declaration: **NOVAMag® SHIELD**

Product	Size	Content	REF
NOVAMag® SHIELD XXS	12 x 12 mm	1 Membrane	721212

Place, Date: Zossen, 24.07.2026



Katja Pratsch
(Director Regulatory Affairs &
Quality Management)



Dr. Drazen Tadic
(PRRC-QA/TD)