Manufacturer's Self-Declaration

in relation to Regulation 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 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	Ferrosan Medical Devices A/S
Manufacturer address and contact details	Sydmarken 5, 2860 Søborg, Denmark
Single Registration Number (SRN) (if available)	DK-MF-000002856

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

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

[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.

We, as the manufacturer declare under our sole responsibility:

- 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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

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

☐ 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)

☐ 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)

☒Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has 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 substitute and a signed written agreement 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

➢ **Up-classified 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:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has 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 substitute and a signed written agreement 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.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- 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:

Ferrosan Medical Devices A/S

Sydmarken 5, 2860 Søborg, Denmark

Camilla Hudtloff, VP QM&RA

Date: 18. JAN. 2024

C. Hudtloff

Schedule of Devices

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

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
SPONGOSTAN™ Standard MS0002 5712123SPONGOSTANspongeTW	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027
SPONGOSTAN™ Anal MS0004 5712123SPONGOSTANanalVV	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027

SPONGOSTAN™ Dental MS0005 5712123SPONGOSTANdentalJM	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027
SPONGOSTAN™ Standard MS0006 5712123SPONGOSTANspongeTW	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027
SPONGOSTAN™ Anal MS0007 5712123SPONGOSTANanalVV	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027

SPONGOSTAN™ Powder MS0008 5712123SPONGOSTANpowderT6	Class III, rule 8 and 18	NA	10000463948-PA-NoMA-DNK Rev 0.0 10000463941-PA-NoMA-DNK Rev 0.0 DNV Product Assurance AS and 2460	26 May 2024	31 December 2027