EU Quality Management System Certificate

Certificate no.:
10000513072-PA-NoMA-DNK

Initial certification date:
14 November 2023

Valid Until:
13 November 2028

This is to certify that the quality system of

Ferrosan Medical Devices A/S

Sydmarken 5, 2860 Søborg, Denmark
SRN: DK-MF-000002856

For design, production, and final product inspection/testing of:

Sterile Absorbable Gelatin Haemostatics

Has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX, (Chapter I & III) of Regulation (EU) 2017/745 on Medical Devices

Place and date:
Høvik, 24 October 2025

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Alessandra Rinna
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Jurisdiction

Application of Regulation 2017/745 on medical devices, implemented in Norway by Act 7 May 2020 no. 37 on medical devices and Regulation 9 May 2021 no.1476 on medical devices by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2630837	14 November 2023
1.0	Adding SURGIFLO™Haemostatic Matrix Kit with Thrombin MS0012	2630835	13 December 2023
2.0	Adding SPONGOSTAN™ Standard, MS0002 SPONGOSTAN™ Standard, MS0006 SPONGOSTAN™ Anal, MS0004 SPONGOSTAN™ Anal, MS0007 SPONGOSTAN™ Dental, MS0005 SPONGOSTAN™ Powder, MS0008	2630834 2630836	04 December 2024
3.0	Adding SURGIFLO™ Haemostatic Matrix Kit with Thrombin, MS0016	3239101	24 October 2025

Products covered by this Certificate:

Product Description (and intended purpose for class IIb)	Product Name	Class*
Absorbable Gelatin Haemostatics Indicated for surgical procedures (except ophthalmic) for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical	SURGIFLO™ Haemostatic Matrix MS0010	III
Indicated in surgical procedures (other than ophthalmic) as an adjunct to haemostasis when control of bleeding ranging from oozing to spurting by ligature or other conventional methods is ineffective or impractical.	SURGIFLO™ Haemostatic Matrix Kit with Thrombin MS0012 SURGIFLO™ Haemostatic Matrix Kit with Thrombin, MS0016	III
SPONGOSTAN™ Standard, used dry or saturated with sterile sodium chloride solution, are indicated for	SPONGOSTAN™ Standard, MS0002 SPONGOSTAN™ Standard, MS0006	III

surgical procedures (except ophthalmic) for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical		
SPONGOSTAN™ Anal, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. SPONGOSTAN™ Anal is suitable for anal surgical procedures due to its shape.	SPONGOSTAN™ Anal, MS0004 SPONGOSTAN™ Anal, MS0007	III
SPONGOSTAN™ Dental, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. SPONGOSTAN™ Dental is suitable for dental surgical procedures due to its shape.	SPONGOSTAN™ Dental MS0005	III
SPONGOSTAN™ Powder, saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for haemostasis, when control of capillary bleeding, oozing bleeding, venous and arteriolar bleeding by pressure, ligature and other conventional procedures are ineffective or impractical.	SPONGOSTAN™ Powder MS0008	III

* Class III and class IIb devices referred to in the second subparagraph of Article 52(4): Technical documentation assessment is covered by a separate EU Technical Documentation Assessment Certificate No.: <xxxxxxx>

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Ferrosan Medical Devices A/S	Sydmarken 5, 2860 Søborg, Denmark

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices and IIb devices falling under Article 52 (4) covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.
- For Custom Made Class III implantable device the certification only relates to the Quality management system. Technical documentation assessment and issuance of EU Technical Documentation Assessment Certificate does not apply.