

This is to certify that the defined representative samples of the device manufactured by:

Ferrosan Medical Devices A/S
Sydmarken 5
2860 Søborg
Denmark

have been approved in conformity with the requirements of


Annex II Section 4 - Examination of the design of the product

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following devices:

Absorbable Gelatin Haemostatics in class III

The Design Examination certificate is valid provided that no changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' terms and conditions of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law. The certificate is based on successful evaluation of the device design.



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2016-09-05
Expires: 2021-09-05
Initial date of issue: 2010-06-04
Reference: Art2a1608v542f758

The following products in class III are covered by the certificate:

SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Film (20 unit)	MS0001
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Standard (20 unit)	MS0002
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Special (20 unit)	MS0003
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Anal (20 unit)	MS0004
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Dental (24 unit)	MS0005
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Standard (2 unit)	MS0006
SPONGOSTAN TM Absorbable Haemostatic Gelatin Sponge, Anal (5 unit)	MS0007
SPONGOSTAN TM Absorbable Haemostatic Gelatin Powder	MS0008
SURGIFLO TM Haemostatic Matrix	MS0010
SURGIFLO TM Haemostatic Matrix Kit with Thrombin	MS0011
SURGIFLO TM Haemostatic Matrix Kit with Thrombin	MS0012

Certificate number: DGM – 711
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Espongostan® Anal (5 unit)

Espongostan® Anal (20 unit)

Espongostan® Film (1 unit)

Espongostan® Film (10 unit)

Espongostan® Film (100 unit)

Gelastyp® (24 unit)

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