

This is to certify that the quality system of:

Ferrosan Medical Devices A/S
Sydmarken 5
2860 Søborg
Denmark

has been approved in conformity with the requirements of:

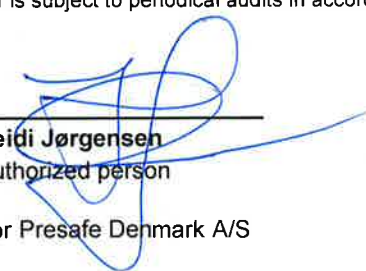
Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design, manufacture and final testing of Absorbable Gelatin Haemostatics in class III

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.



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 product families in class III are covered by the certificate and by EC design examination certificate DGM-711:

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

Certificate number: DGM – 710
Certificate type: EC Certificate

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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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