

EU Declaration of Conformity

Legal Manufacturer	Ferrosan Medical Devices A/S. Sydmarken 5 2860 Søborg Denmark SRN: DK-MF-000002856
Product Name	<ul style="list-style-type: none"> • SPONGOSTAN™ Standard • SPONGOSTAN™ Anal • SPONGOSTAN™ Dental
EU Product Classification according to Annex VIII	Class III according to the rules 8 and 18
Product Family	Sterile Absorbable Gelatin Haemostatics
Intended Purpose SPONGOSTAN™ Standard	SPONGOSTAN™ Standard, 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.
Intended Purpose SPONGOSTAN™ Anal	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.
Intended Purpose SPONGOSTAN™ Dental	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.

Basic UDI-DI	5712123SPONGOSTANspongeTW
Conformity Assessment Procedure	Annex IX
Notified Body Name and Number	DNV Product Assurance AS (NB 2460)
Notified Body Certificate Type and Number	Technical Documentation: C564464 Full Quality Assurance: 10000513072-PA-NoMA-DNK

List of devices covered by this Declaration of Conformity:

Product code(s)	Device name(s)
MS0002	SPONGOSTAN™ Standard (20 unit)
MS0004	SPONGOSTAN™ Anal (20 unit)
MS0005	SPONGOSTAN™ Dental (24 unit)
MS0006	SPONGOSTAN™ Standard (2 unit)
MS0007	SPONGOSTAN™ Anal (5 unit)

This declaration is issued according to the Medical Device Regulation (EU) 2017/745 under the sole responsibility of **Ferrosan Medical Devices A/S**.

Ferrosan Medical Devices A/S declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

I hereby declare that the above-mentioned devices are in conformity with the Medical Device Regulation (EU) 2017/745,


 Joan Drejer
 Director, Regulatory Affairs
 Ferrosan Medical Devices A/S

Søborg 13.12.2024
 Place and date (dd.mm.yyyy) of issue: