

## EC Declaration of Conformity

(Issued according to Medical Devices Directive 93/42/EEC, as last amended by directive 2007/47/EC)

We hereby declare that the devices mentioned below fall within class III and meet the provisions of Medical Devices Directive of the European Union, 93/42/EEC as last amended under directive 2007/47/EC. We also declare that conformity assessment procedure is carried out according to annex II of the directive and implemented quality management system, complying ISO 13485:2016 & EN ISO 13485:2016. The manufacturer is solely responsible for the declaration of conformity.

**Manufacturer** : AEGIS LIFESCIENCES PVT. LTD.  
**Address** : 215/216, Mahagujarat Industrial Estate-382213, Ahmedabad, Gujarat, India.  
**EUDAMED SRN** : IN-MF-000024058  
**Number/Actor ID**

**EC representative** : Obelis S.A  
**Address** : Bd. General Wahis 53, 1030 Brussels, Belgium.  
**EUDAMED SRN** : BE-AR-000000106  
**Number/Actor ID**

**Product Name** : SURGISPON®  
**Generic Name** : Gelatin based, sterile, absorbable, haemostatic sponge for surgical use  
**Intended Purpose/Use** : The above mentioned product is gelatin based, sterile, absorbable, topical haemostatic for use in various surgical procedures where traditional haemostatic is difficult or impractical and use of other non-absorbable materials is undesirable. It is manufactured from highly purified pharmaceutical grade gelatin.

**GMND Code** : 48170  
**Class** : III (Rule 17 of Annex IX, MDD 93/42/EEC)  
**Basic UDI-DI** : 890603845AGSNM

<b>Notified Bodies</b>	: Notified Body Name	DNV Product Assurance AS	CE Certificates
	: Identification number of the notified body	NB 2460	
	: Notified Body Name	BSI Group The Netherlands B.V.	ISO 13485:2016 & EN ISO 13485:2016 Certificate
	: Identification number of the notified body	NB 2797	

**Sizes/Model/Type** As given in below table.

S. No.	Product Id	Product Name	Dimensions (mm)
1.	SSP-705010	REGULAR	70 x 50 x 10
2.	SSP-805010	STANDARD	80 x 50 x 10
3.	SSP-101010	DENTAL CUBES	10 x 10 x 10
4.	SSP-8030	ANAL TAMPON	80 x 30 Ø
5.	SSP-802010	STRIP	80 x 20 x 10
6.	SSP-705001	SPECIAL	70 x 50 x 01
7.	SSP-805001	SPECIAL	80 x 50 x 01
8.	SSP-151515	DENTAL	15 x 15 x 15
9.	SSP-01	POWDER	1 gram

SURGISPON® - SSP

**Standards applied:** EN 556-1:2001, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-4:2009 EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 13485:2016, EN ISO 14155:2020, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 22442-1:2020, EN ISO 22442-2:2020, EN ISO 22442-3: 2007, ISO 10993-10: 2021, ISO 14644 - 1: 2015, ISO 14644-2:2015, UNITED STATES PHARMACOPOEIA - 43.

**Conformance Certificate details:**

**CE Certificate** : 241608-2017-CE-IND-NA-PS Rev. 2.0

**Design Approval Certificate** : 242606-2017-CE-IND-NA-PS Rev. 2.0

**ISO 13485:2016 & EN ISO 13485:2016 Certificate** : MD 766456

**Valid Until: 27 May 2024**

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**Expiry Date: 2022-10-24**

For Aegis Lifesciences Pvt. Ltd.

**Authorized Signatory:**

**Name** : Mr. Bhavin Trivedi  
**Position** : Authorized Signatory  
**Date** : 06/09/2022  
**Place** : Ahmedabad, India.



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