



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 13485:2012. The manufacturer is solely responsible for the declaration of conformity.

Manufacturer : **AEGIS LIFESCIENCES**, 215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, India.

EC representative : **M/s. WELLKANG Ltd.**, Suite B, 29 Harley Street, London W1G 9QR, England, UK

Product Name : SURGISPON

Generic Name : Gelatin based, sterile, absorbable, haemostatic sponge for surgical use

Device Description : SURGISPON 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 first extract grade gelatin

GMDN code : 48170

Class : III (Rule 17 of Annex IX, MDD 93/42/EEC)

Notified Body : DNV GL Nemko Presafe AS, Veritasveien 3, 1363 Høvik, Norway

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

Sr. No.	Product ID	Model Name	Dimensions (MM)
1.	SSP - 805010	STANDARD	80×50×10
2.	SSP - 705010	REGULAR	70×50×10
3.	SSP - 8030	ANAL TAMPON	80×30 Ø
4.	SSP - 101010	DENTAL CUBES	10×10×10
5.	SSP - 202007	DENTAL	20×20×07
6.	SSP - 801507	NASAL	80×15×07
7.	SSP - 8007	NASAL TAMPON	80× 07 Ø
8.	SSP - 602007	SIZE 12-7	60×20×07
9.	SSP - 100	SIZE 100	125×80×10
10.	SSP - 01	POWDER	1 gram



AEGIS LIFESCIENCES

PROTECTION THROUGH PERFECTION
ISO 9001 : 2008, ISO 13485 : 2003 & GMP Certified



11.	SSP - 705001	SPECIAL	70×50×01
12.	SSP - 805001	SPECIAL	80×50×01
13.	SSP - 200705	FILM	200×70×0.5

Standards applied: EN 556-1:2001, EN ISO 15223-1:2012, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10: 2010, ISO 10993-11:2009, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2009, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 22442-1:2007, EN ISO 22442-2:2007, EN ISO 22442-3:2007

Certificate details:

CE Certificate: 241608-2017-CE-IND-NA-PS Rev. 0.0

Design Approval Certificate: 242606-2017-CE-IND-NA-PS Rev. 0.0

Quality Management System Certificate: 133673-2013-AQ-IND-NA

Signature:

Name : Ms. Neelam Gupta
Position : Managing Partner
Date : 14th April, 2017
Place : Ahmedabad, India.

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