

## 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-382 213, 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** : Surgi-ORC®  
**Generic Name** : Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable  
**Intended Purpose/Use** : Above mentioned product is made from viscose material derived from plant based cellulose. This Product is used adjunctively in various surgical procedures to assist when control of bleeding from capillary, venous and small arteriolar vessels, by pressure, ligature and other conventional procedures is either ineffective or impractical. The Surgi-ORC® haemostat can be cut to size in endoscopic procedures.

**GMDN Code** : 38771  
**Class** : III (Rule 8, Annex IX, MDD 93/42/EEC)  
**Basic UDI-DI** : 890603845ORCQU

<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.

Sr. No.	Model Variant	Product ID	Dimensions (in cm)
1.	Original / Standard	SOO-0214	5 × 35
2.		SOO-0408	10 × 20
3.		SOO-0304	7.5 × 10
4.		SOO-0203	5 × 7.5
5.		SOO-0228	5 × 7
6.		SOO-502	1.25 × 5
7.	Knit	SOK-0304	7.6 × 10.2
8.		SOK-0609	15.2 × 23
9.		SOK-0101	2.6 × 2.6
10.	Fibril	SOF-0102	2.6 × 5.1
11.		SOF-0204	5.1 × 10.2
12.		SOF-0404	10.2 × 10.2
13.	Non-Woven / SNOW	SON-0102	2.6 × 5.1
14.		SON-0204	5.1 × 10.2
15.		SON-0404	10.2 × 10.2

Doc. No.: AL/ECDOC/ORC/PRM/POL/R8, Date of revision: 07/07/2023

Page 1 of 2

**Standards applied:** : EN 556-1:2001, 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 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, EN ISO 10993-23:2021, 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, ISO 20417:2021, UNITED STATES PHARMACOPOEIA – 43.

**Conformance Certificate details:**

<b>CE Certificate</b>	<b>: 10000384931-PA-NA-IND Rev 2.0</b>	<b>Valid Until: 27 May 2024</b>
<b>Design Approval Certificate</b>	<b>: 10000428353-PA-NA-IND Rev 2.0</b>	<b>Valid Until: 27 May 2024</b>
<b>ISO 13485:2016 &amp; EN ISO 13485:2016 Certificate</b>	<b>: MD 766456</b>	<b>Expiry Date: 2025-10-24</b>

**For Aegis Lifesciences Pvt. Ltd.**

**Authorized Signatory:**

  


**Name** : Mr. Bhavin Trivedi  
**Position** : Authorized Signatory  
**Date** : 13/07/2023  
**Place** : Ahmedabad, India.

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Page 1 of 2