EUCARE PHARMACEUTICALS PRIVATE LIMITED

Regd Office & Factory : Plot No. AC-25B, SIDCO Industrial Estate,
Thirumudivakkam, Chennai - 600 132, INDIA, Tel. : +91-44-4598 9955, 9910, 9939
E-mail : info@eucareindia.com, Website : www.eucareindia.com, www.eucare.in
Corporate Identification No.U24231TN1996PTC034848

DECLARATION OF CONFORMITY

Serial No.: SCF/015/21-22

Manufacturer	**EUCARE PHARMACEUTICALS (P) LTD.** AC-25B, SIDCO, Industrial Estate, Thirumudivakkam, Chennai – 600132, India. Tel.: +91-44-4598 9955, 9910, 9939 E-mail: info@eucareindia.com
European Authorized Representative	**Obelis.S.a** Bd. Général Wahis 53, 1030 Brussels, Belgium, Phone: 32.2.732.59.54 Fax: 32.2.732.60.03, E-mail: mail@obelis.net Representative: **Mr. Gideon ELKAYAM**

Description of the Product

Name of the product	Sterile Haemostatic Absorbable Gelatin Sponge-USP
Brand Name	**SCROFALON**
Batch No.	GP2111154
Product Code	SCFS 1013
Dimension	10x10x10mm
Mfg. Date.	Nov-21
Expiry Date	Oct-26
Quantity	30000 No's
Classification	III
Classification Route	Rule17 in accordance of the council directive MDD 93/42/EEC of 14 June 1993
Conformity Assessment Route	Annex 2, Full Quality Assurance

We hereby ensure and declare that the product mentioned above conforms to the provision of **MDD 93/42/EEC** directive. All supporting documentation is retained within the premises of the manufacturer.

Conformity Assessment Body	DNV Product Assurance AS Veritasveien 3, N-1363 Høvik, Norway		
Certificate No.	**10585-2017-CE-IND-NA-PS Rev. 2.0**	Date of Certificate	**11 November 2020**

Authorized signatory for EUCARE PHARMACEUTICALS (P) LTD.,

Signature :
Name : Muthu Dhandapani
Position : Head – Quality and Regulatory Affairs
Date : 29.11.2021

EUCARE PHARMACEUTICALS PVT. LTD. Chennai - 600 132

	I. LIST HARMONIZED STANDARDS	
#	Standard	Description
1.	MDD 93/42/EEC as amended by 2007/47/EC	Medical Device Directive
2.	EN ISO 13485:2016	Medical Devices – Quality Management Systems requirements for regulatory purposes
3.	EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process
4.	EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Test for Genotoxicity, carcinogenicity and reproductive toxicity
5.	EN ISO 10993-4:2009	Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood
6.	EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in-vitro cytotoxicity and bacterial Endotoxins
7.	EN ISO 10993-6:2009	Biological evaluation of medical devices – Part 5: Test for local effect after implantation.
8.	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
9.	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
10.	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly process.
11.	EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
12.	EN ISO 11737-1:2006	Sterilization of medical devices – Microbiological methods – Part 2: Test of sterility performed in the definition, validation, and maintenance of a sterilization process.
13.	EN ISO 11137-1:2015	Sterilization of health care products – Radiation — Part 1: Requirements for development, validation and routine control of sterilization process for medical devices.
14.	EN ISO 11137-2:2015	Sterilization of health care products - radiation - Part 2: Establishing the sterilization dose
15.	EN ISO 14971:2012	Medical Device - Application of risk Management to Medical Devices
16.	EN ISO 22442-1:2007	Medical devices utilizing animal tissues and their derivatives - Application of risk management.
17.	EN ISO 22442-2:2007	Medical devices utilizing animal tissues and their derivatives - Control on sourcing, collection and handling
18.	EN ISO 22442-3:2007	Medical devices utilizing animal tissues and their derivatives - Validation of the elimination and / or inactivation of viruses and TSE agents
19.	EN ISO 15223-1:2016	Symbols for use in the labeling of medical device.
20.	EN 1041:2008	Information supplied by the manufacturer of medical devices.

21.	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
22.	EN 62366:2008 IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
23.	EN ISO 14155: 2011	Clinical investigation of Medical Devices for Human subject/good clinical practices
	II. OTHER APPLICABLE STANDARDS/GUIDELINES	
24.	ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Test for Skin sensitization and skin irritation.
25.	MEDDEV 2.7.1 rev.4	Guidelines on medical devices - Clinical evaluation.
26.	MEDDEV 2.12-1 rev.8	Guidelines on medical devices -Vigilance System.
27.	MEDDEV 2.12/2 rev.2	Guidelines on medical devices –Post Market Clinical Follow-up studies.
28.	NB-MED 2.12/Rec 1	Post - Market Surveillance (PM) Post Market / production.
29.	Indian Pharmacopoeia British Pharmacopoeia United States Pharmacopeia	Finished product analysis Test for Sterility, Purified water analysis
30.	ISO 14644:2015	Cleanrooms and associated controlled environments
31.	ICH E6(R1)	Guideline for Good Clinical practice
32.	ICH E6(R2)	Consensus guideline

*Non-harmonized standards have been followed for the domain which does not harmonized standard yet available in the published latest official journal.

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DECLARATION OF CONFORMITY

Serial No.: SCF/014/21-22

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Description of the Product

Name of the product	Sterile Haemostatic Absorbable Gelatin Sponge-USP
Brand Name	**SCROFALON**
Batch No.	GP2111153
Product Code	SCFS 1013
Dimension	10x10x10mm
Mfg. Date.	Nov-21
Expiry Date	Oct-26
Quantity	24400 No's
Classification	III
Classification Route	Rule17 in accordance of the council directive MDD 93/42/EEC of 14 June 1993
Conformity Assessment Route	Annex 2, Full Quality Assurance

We hereby ensure and declare that the product mentioned above conforms to the provision of **MDD 93/42/EEC** directive. All supporting documentation is retained within the premises of the manufacturer.

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