

EC DESIGN

Examination Certificate

Certificate No.:
10831-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-250092-2010-PRC-IND

Valid Until:
27 May 2024

This is to certify that:

Sterile Haemostatic Absorbable Gelatin Sponges

Manufactured by:

EUCARE PHARMACEUTICALS (P) LTD

**Plot No. AC 25 B, Sidco Industrial Estate, Thirumudivakkam,
CHENNAI 600 132, India**

Has been assessed with respect to:

**EXAMINATION OF THE DESIGN OF THE PRODUCT AS
DESCRIBED IN ANNEX II SECTION 4 OF COUNCIL
DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 November 2020

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Mariann Jeremiassen

Mariann Jeremiassen

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
10831-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-250092-2010-PRC-IND

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Issue Date |
|------------|---|-------------------------|
| 0.0 | Replace Certificate no. 7617-2015-CE-IND-D rev.1.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460), issued after addition of two new brands. | 24 July 2017 |
| 1.0 | Re issuing the Certificate with QR Code | 1 July 2020 |
| 2.0 | Recertification | 12 November 2020 |

Products covered by this Certificate:

| Type of medical device and identification no.: | Medical Device Class: |
|---|-----------------------|
| Sterile Haemostatic Absorbable Gelatin Sponges With following variants 1. Standard 2. Anal 3. Special 4. Film 5. Dental Brand Names: 1. Gelspon –P 2. Scrofolon 3. Galenaspon 4. Medisponge 5. Urgospon 6. Gelbond | III |
| Short description of the Medical Device: Sterile Haemostatic Absorbable Gelatin Sponge – It is a surgical haemostatic sponge, manufactured from highly purified neutral gelatine material exclusively from porcine origin for use in various surgical procedures, where traditional haemostasis is difficult and impractical use of other non-absorbable material is undesirable. Available in different convenient dimensions in gamma sterilized forms with suitable double sterile packaging. The entire content of pack is sterilized by gamma Irradiation. | |

Certificate No.:
10831-2017-CE-IND-NA-PS Rev. 2.0

Project No.:
PRJC-250092-2010-PRC-IND

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate