DNV·GL

EC DESIGN

Examination Certificate

Certificate No.:	Project No.:	Valid Until:
10000428353-PA-NA-IND Rev 2.0	PRJC-521018-2015-MSL-IND	27-May-2024

This is to certify that:

OXIDIZED REGENERATED CELLULOSE HAEMOSTAT, STERILE, ABSORBABLE

Manufactured by:

Aegis Lifesciences Pvt. Ltd.

215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, 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, 03 March 2021

Digitally signed by Chitic Ecaterina
Date: 2022.06.15 08:39:43 EEST
Reason: MoldSign Signature
Location: Moldova

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Mariann Jeremiassen

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

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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	Original Certificate	2021-03-01
1.0	Editorial changes	2021-03-02
2.0	**Editorial changes**	**2021-03-03**

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable	III	38771
Short description of the Medical Device:		
The therapeutic indications of Surgi-ORC®, the sterile, absorbable oxidized regenerated cellulose (ORC) haemostat, is intended to be used in various surgeries for haemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. ORC Haemostat is designed to arrest capillary bleeding and bleeding from parenchymatous organs and resection areas at surgical interventions. It is suitable for use in general surgery and digestive surgery, neurosurgery (especially cerebral operations), plastic surgery, orthopaedic, gynaecology, urology, stomatology, traumatology, and many other branches of surgery. ORC Haemostat can be applied into cavities (after extirpation of tumours) as well as endoscopic interventions or dental praxis. The haemostatic action of ORC is by formation of a gelatinous mass upon saturation with blood, which leads to formation of a stable clot and action mechanism of ORC haemostat is independent from blood coagulation mechanism of the body. Surgi-ORC® is supplied as Original/Standard (loose knit), Knit (density woven knit), Fibril (Lightweight, soft, layered structure) and Non-woven/SNOW (structured non-woven). Surgi-ORC® is sterilized by Gamma Irradiation.		

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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 change of the products detailed above 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