**LISMEDFARM S.R.L.**
Șos. Muncești, 167/B, MD – 2002, mun. Chișinău, Republica Moldova
tel.: 022-80-47-98, 022-55-64-38, 022-56-94-91, e-mail: oficiu@lismedfarm.md,
web: https://lismedfarm.md, c/f: 1003600113573, TVA: 0304618, director – Ecaterina Chitic

*Anexa nr. 1*
*La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE*

**Către** Agenția Medicamentului
și Dispozitivelor Medicale

**NOTIFICARE**
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2023.09.26_10.30/1 din 2023.05.29

Solicitantul S.R.L. Lismedfarm, cu sediul 167/B, șos. Muncesti, MD-2002 Chișinău, mun. Chișinău, Moldova, tel./fax: 022804798, 079981005, e-mail: calitate@lismedfarm.md, vlad.chitic@lismedfarm.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a producătorului Aegis Lifesciences Pvt. Ltd., India:
Membrană hemostatică „SURGI-ORC”.

Se anexează următoarele acte:
Declarația de proprie răspundere (DC/GOV/2) din 2023.05.29
Declarație de Conformitate UE nr. AL/ECDOC/ORC/R4 din 2022.04.15
Autorizația de reprezentația nr. f/n din 2022.08.23
Certificat UE FQA nr. 10000384931-PA-NA-IND Rev.2.0 din 2021.03.03
Certificat UE TDA nr. 10000428353-PA-NA-IND Rev 2.0 din 2021.03.03
Lista dispozitivelor medicale solicitate spre notificare (cantitate: 32)

Director executiv, Chitic Vlad, Semnătura _____

Digitally signed by Chitic Vlad
Date: 2023.05.29 12:24:55 EEST
Reason: MoldSign Signature
Location: Moldova

**Tabelul de recepționare a notificării**
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

| | |
|---|---|
| Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului | |
| Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării) | |
| Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului | |
| Semnătura persoanei responsabile | |

**LISMEDFARM S.R.L.**
Șos. Munceşti, 167/B, MD – 2002, mun. Chișinău, Republica Moldova
tel.: 022-80-47-98, 022-55-64-38, 022-56-94-91, e-mail: oficiu@lismedfarm.md,
web: https://lismedfarm.md, c/f: 1003600113573, TVA: 0304618, director – Ecaterina Chitic

*Anexa nr. 2*
*La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE*

**Către** Agenția Medicamentului
și Dispozitive Medicale

**DECLARAŢIE PE PROPRIE RĂSPUNDERE**
la Notificare pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 2023.09.26_10.30/1 din 2023.05.29

Solicitant: Chitic Vlad, cu sediul ap. 12, str. Mitropolit Petru Movila 23/9, MD-2004 Chișinău, mun. Chișinău, directorul executiv al Lismedfarm S.R.L., declar pe proprie răspundere, cunoscând prevederile art. 352[1], Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivele medicale a producătorului Aegis Lifesciences Pvt. Ltd., India:
Membrană hemostatică „SURGI-ORC”.

**Sunt autentice și corespund realității.**

Data 2023.05.29

Director executiv, Chitic Vlad, Semnătura _____

# 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 Number/Actor ID** : IN-MF-000024058

**EC representative** : OBELIS S.A
**Address** : Bd. General Wahis 53, 1030 Brussels, Belgium.
**EUDAMED SRN Number/Actor ID** : BE-AR-000000106

**Product Name** : Surgi-ORC®
**Generic Name** : Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable
**Intended Purpose/Use** : The above mentioned 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.
**GMND Code** : 38771
**Class** : III (Rule 8, Annex IX, MDD 93/42/EEC)

| | | | |
|---|---|---|---|
| **Notified Bodies** | : 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 |
|---|---|---|---|
| 1. | Original / Standard | SOO-0214 | 2 inch X 14 inch (5.1 cm X 35.6 cm) |
| 2. | | SOO-0408 | 4 inch X 8 inch (10.2 cm X 20.3 cm) |
| 3. | | SOO-0203 | 2 inch X 3 inch (5.1 cm X 7.6 cm) |
| 4. | | SOO-502 | 0.5 inch X 2 inch (1.3 cm X 5.1 cm) |
| 5. | | SOO-0102 | 1 inch X 2 inch (2.5 cm X 5.1 cm) |
| 6. | | SOO-0304 | 3 inch X 4 inch (7.6 cm X 10.1 cm) |
| 7. | | SOO-0205 | 2 inch X 5 inch (5.1 cm X 12.7 cm) |
| 8. | | SOO-0101 | 1 inch X 1 inch (2.5 cm X 2.5 cm) |
| 9. | | SOO-66 | 0.6 inch X 0.6 inch (1.5 cm X 1.5 cm) |
| 10. | Knit | SOK-0203 | 2 inch X 3 inch (5.1 cm X 7.6 cm) |
| 11. | | SOK-0304 | 3 inch X 4 inch (7.6 cm X 10.2 cm) |
| 12. | | SOK-0609 | 6 inch X 9 inch (15.2 cm X 22.9 cm) |
| 13 | | SOK-0101 | 1 inch X 1 inch (2.5 cm X 2.5 cm) |
| 14. | | SOK-0103 | 1 inch X 3 inch (2.5 cm X 7.6 cm) |
| 15. | | SOK-0135 | 1 inch X 3.5 inch (2.5 cm X 8.9 cm) |



AEGIS LIFESCIENCES PRIVATE LIMITED Regd Office : 215/216, Mahagujrat Industrial Estate, Moraiya, Ahmedabad-382213. Gujarat, India,
CIN-U24302GJ2019PTC106437 Tel : +91 9726903131 / 9727103131 www. aegis-lifesciences.com E-mail : aegis.lifesciences@gmail.com

| | | | |
|---|---|---|---|
| 16. | | SOK-0102 | 1 inch X 2 inch (2.5 cm X 5.1 cm) |
| 17. | | SOK-0204 | 2 inch X 4 inch (5.1 cm X 10.2 cm) |
| 18. | | SOK-0404 | 4 inch X 4 inch (10.2 cm X 10.2 cm) |
| 19. | | SOK-5608 | 5.6 inch X 8 inch (14.2 cm X 20.3 cm) |
| 20. | Fibril | SOF-0102 | 1 inch X 2 inch (2.5 cm X 5.1 cm) |
| 21. | | SOF-0204 | 2 inch X 4 inch (5.1 cm X 10.2 cm) |
| 22. | | S0F-0404 | 4 inch X 4 inch (10.2 cm X 10.2 cm) |
| 23. | | SOF-0203 | 2 inch X 3 inch (5.1 cm X 7.6 cm) |
| 24. | | SOF-0304 | 3 inch X 4 inch (7.6 cm X 10.2 cm) |
| 25. | | SOF-0202 | 2 inch X 2 inch (5.1 cm X 5.1 cm) |
| 26. | | SOF-0101 | 1 inch X 1 inch (2.5 cm X 2.5 cm) |
| 27. | Non-Woven / SNOW | SON-0102 | 1 inch X 2 inch (2.5 cm X 5.1 cm) |
| 28. | | SON-0204 | 2 inch X 4 inch (5.1 cm X 10.2 cm) |
| 29. | | S0N-0404 | 4 inch X 4 inch (10.2 cm X 10.2 cm) |
| 30. | | SON-0203 | 2 inch X 3 inch (5.1 cm X 7.6 cm) |
| 31. | | SON-0304 | 3 inch X 4 inch (7.6 cm X 10.2 cm) |
| 32. | | SON-0202 | 2 inch X 2 inch (5.1 cm X 5.1 cm) |

**Standards applied:** UNITED STATES PHARMACOPOEIA 43, EN 556-1: 2001, EN 1041: 2008, 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 10993-11: 2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, 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, ISO 10993-10: 2021, ISO 14644-1:2015, ISO 14644-2:2015.

**Conformance Certificate details:**

| | | |
|---|---|---|
| **CE Certificate** | **: 10000384931-PA-NA-IND Rev 2.0** | **Valid Until: 27 May 2024** |
| **Design Approval Certificate** | **: 10000428353-PA-NA-IND Rev 2.0** | **Valid Until: 27 May 2024** |
| **ISO 13485:2016 & EN ISO 13485:2016 Certificate** | **: MD 766456** | **Expiry Date: 2022-10-24** |

**For Aegis Lifesciences Pvt. Ltd.**

**Authorized Signatory:**


**Name** : **Mr. Bhavin Trivedi**

**Position** : **Authorized Signatory**

**Date** : 15/04/2022

**Place** : Ahmedabad, India.



AEGIS LIFESCIENCES PRIVATE LIMITED Regd Office : 215/216, Mahagujrat Industrial Estate, Moraiya, Ahmedabad-382213. Gujarat, India,
CIN-U24302GJ2019PTC106437 Tel : +91 9726903131 / 9727103131 www. aegis-lifesciences.com E-mail : aegis.lifesciences@gmail.com

**ATTACHMENT № 2 FROM 2022.08.23**
**TO SALES OF GOODS CONTRACT № LMF/IMP/EUMDD/IND/1 FROM 2022.08.23**
**APPOINTMENT ON HANDLING "GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM" IN THE TERRITORY**

Company **Lismedfarm S.R.L.**, represented by **executive director Vlad Chitic**, hereinafter name the "Buyer", from one side, empowered by the Empowerment nr. 3 from 02.11.2020, and company SELLER_Aegis Lifesciences Pvt. Ltd., represented by SELLER_REP_Rajeev Gupta, hereinafter name the "Seller" from the other side, empowered by the SELLER_EMPOWERMENT, collectively named "Parties", have concluded this Attachment to the Contract as follows, regarding the safe handling of the select medical devices (hereinafter called "Goods") manufactured and supplied by Seller to Buyer in order to comply with the requirements of the Republic of Moldova Government Decision no. 702 of 11.07.2018 concerning Medical Devices (GDMD) and the "Guidelines on a Medical Devices Vigilance System":

## APPOINTMENT

The Seller hereby appoints Buyer upon the terms and conditions herein contained to be the Authorized Representative for select Goods manufactured by the Seller. The list of the Goods is indicated in Attachment 1 to this Contract "List of Goods for Exclusivity of Import and Distribution per Part 9 of the Contract".

The Buyer expresses their desire to enter into an agreement with the Seller upon the terms and conditions set forth in this Agreement.

## RESPONSIBILITIES OF BOTH PARTIES - GENERAL INFORMATION

The Buyer is authorized to perform registration, renewal, variation of the registration.

The Buyer shall be responsible for registering, monitoring and communicating all customer and market-related claims for the customers and market related about the Goods of the Seller and to notify the Seller upon receiving such claims.

The Buyer has the right to unilaterally, on short notice, terminate his mandate as the Authorized Representative for the Seller's Goods if the Seller acts contrary to his obligations stipulated by the EU MDR/IVDR.

The Seller will implement the Unique Device Identification (UDI) System for his Goods as prescribed by the EU MDR/IVDR and assign his Goods with Unique Device Identification Device Identifiers (UDI-DI).

The Seller shall provide the following information to the Buyer for the registration of medical devices:

a) EU Declaration of Conformity,
b) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data,
e) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency of the Republic of Moldova (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
h) Incident reports and reports on corrective actions taken,
i) UDI-DI;

## INCIDENT REPORTING

The Buyer shall maintain an up-to-date Quality System and communicate the vigilance procedures to the Seller for coordination and continuity of the Seller's own Quality System. Buyer shall communicate any other procedures upon the request of the Seller.

The Buyer shall work closely with the Seller and shall transmit without delay any information coming from the Agency. In case of special request by the Agency, particularly in relation with incidents reporting, the Buyer will agree with the Seller on the position statement and the answers to be given to the Agency.

In case of difference in positions between the Seller and the Buyer, the position of the Seller will prevail and will be supplied to the Agency with a format endorsement of the Seller.

The Buyer shall have a qualified person to be in contact with the Agency.

In case of incidents known first by the Seller, the Buyer will be immediately informed. The Buyer will immediately perform incident analysis with the Seller. The Buyer will write and send to the Agency the initial report including the Seller's actions if available such as sample analysis, analysis of historic lot record and potential corrective actions to be taken in the further manipulation of the product like withdrawal or recall from the market.

The Buyer shall notify Agency within the following time lines applied in case of:

a) Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 (two) calendar days after communication by the Seller of this threat.

b) Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the Seller established a link between the device and the event but not later than 10 (ten) calendar days following the date of awareness of the event.

c) Others: IMMEDIATELY (without any delay that could not be justified) after the Seller established a link between the device and the event but not later than 30 (thirty) calendar days following the date of awareness of the event.

If after becoming aware of a potential reportable INCIDENT there is still uncertainty about whether the event is reportable, Seller must submit a report with the timeframe required for the type of INCIDENT.

As soon as information and incidents assessment from the Seller are available, the Buyer writes and sends the final incidents report. In any case, the Buyer submits these reports to the Seller for preliminary approval. The Buyer will keep these records available for the Agency.

According to the stipulation of medical equipment plant GDMD, the Seller must summarize the experience of manufacturing Goods, take proper measures, and must have the right to know that an incident occasionally happened, and to take proper measures.

a) The mangle of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to lead to the death of patients and users and deterioration of health condition.

b) The above-mentioned, the technical property of the Goods or the problems in medicine, the company has the right to recall the Goods of the same lot and specification.

*Field safety notice*

If the Seller finds a problem with quality of the Goods on the market, it should immediately give out a Field Safety Notice to the users, for them to be able to take the necessary measures (including the recall of the products).

*Recall*

In case the Goods are withdrawn from the market, the Seller should recall the Goods immediately. Before recalling the Goods, the Buyer should inform the Agency.

*Return the products to the company*

The Seller shall send advisory notice to the Buyer and order it to cease selling the Goods, to inform the local governing department and to recall the Goods sold to the market or to inform the users.

After the Buyer recalls the Goods, the Seller should agree with the Buyer on the mode and time of return of the Goods to

the Seller for disposal.

## TRACEABILITY OF SOLD PRODUCTS

The Seller shall keep records of serial numbers, serial or production lot number numbers for all Goods delivered to the Buyer.

The Buyer shall keep records of the Goods delivered to the users or distributors. In this case the traceability of sold Goods can be performed at any time upon request. Records shall include the following information:

a) Date of transfer of the Goods to the customer;
b) Name and address of the customer;
c) Product identification (Commercial name/Model/Catalogue REF/UDI-DI);
d) Batch, serial number;
e) Quantity dispatched;

It is agreed that these records should be available for inspection upon request by the Seller or by the relevant authorities.

## TECHNICAL DOCUMENTATION

The Seller shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the Goods manufactured by Seller to be able to comply with the GDMD requirements.

The Seller shall transfer the agreed Technical documentation and Declaration of Conformity to the Buyer.

The Buyer shall keep the Technical Documents including the Declaration of Conformity available to the Agency for at least five years after the last Goods have been sold.

The Seller shall provide the Buyer with additional documentation if required by Agency.

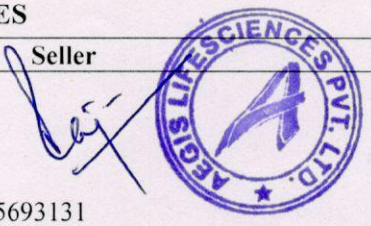
## INSTRUCTION MANUAL

The Seller shall be responsible for content of instructions manual (user's guide) and shall ensure the availability of the English version of the instruction's manual for the Buyer.

The Buyer shall ensure that the required instruction manuals are provided to the customer in official language of the Republic of Moldova.

## RESPONSIBLE PERSONS OF THE PARTIES

| **Buyer** | **Seller** |
|---|---|
| Name: Vlad<br>Surname: Chitic<br>Function: Executive director<br>Stationary phone: ----------<br>Mobile phone: +37379981005<br>E-mail: vlad.chitic@lismedfarm.md<br>Other contact channels:<br>Viber +37379981005<br>WhatsApp +37379981005<br>Signal +37379981005 | Name: Rajeev<br>Surname: Gupta<br>Function: CEO<br>Stationary phone:<br>Mobile phone: +91 9825693131<br>E-mail: aegis.lifesciences@gmail.com<br>Other contact channels:<br>Viber<br>WhatsApp +91 9825693131<br>Signal |



**Buyer**

**Seller**

**ATTACHMENT № 1 FROM 2022.08.23**
**TO SALES OF GOODS CONTRACT № LMF/IMP/EUMDD/IND/1 FROM 2022.08.23**
**LIST OF GOODS FOR EXCLUSIVITY OF IMPORT AND DISTRIBUTION PER PART 9 OF THE CONTRACT**

| N | Generic Device Group† | Commercial name/Trademark | Model | Reference number (GMDN CODE) |
|---|---|---|---|---|
| 1 | Absorbable haemostatic gelatin sponge | SURGISPON | SSP-101010, SSP-805010, SSP-705010 | 48170 |
| 2 | Absorbable haemostatic oxidized regenerated cellulose | SURGI-ORC | * | 38771 |

Using "*" in column "Generic Device Group" means "ALL Generic Device Groups and Products of the Manufacturer"
Using "*" in column "Commercial name/Trademark" means "ALL Commercial name/Trademark of the Generic Device Group"
Using "*" in column "Model" means "ALL Models of that Commercial/Brand name"
Using "*" in column "Reference number" means "ALL Reference numbers of that Commercial/Brand name"

† - According to the European Medical Device Nomenclature (EMDN) version 1.2.

**Buyer**

**Seller**

DNV·GL

# EC CERTIFICATE

## Full Quality Assurance System

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| 10000384931-PA-NA-IND Rev 2.0 | PRJC-521018-2015-MSL-IND | 27-May-2024 |

This is to certify that the quality system of:

# Aegis Lifesciences Pvt. Ltd.

### 215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, India

For design, production and final product inspection/testing of:

**OXIDIZED REGENERATED CELLULOSE HAEMOSTAT, STERILE, ABSORBABLE**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II 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**

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

Certificate No.:
10000384931-PA-NA-IND Rev 2.0

Project No.:
PRJC-521018-2015-MSL-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 | Original Certificate | 2021-03-01 |
| 1.0 | Editorial changes | 2021-03-02 |
| **2.0** | **Editorial changes** | **2021-03-03** |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| Oxidized Regenerated Cellulose Haemostat, Sterile, Absorbable | Surgi-ORC®<br>- Original/Standard<br>- Knit<br>- Fibril<br>- Non-woven/SNOW | III* |

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 10000428353-PA-NA-IND

**Sites covered by this certificate**

| Site Name | Address |
|---|---|
| Aegis Lifesciences Pvt. Ltd. | 215/216, Mahagujarat Industrial Estate-382 213, Ahmedabad, Gujarat, India |

**EU Representative**

**OBELIS S.A (www.obelis.net) Bd. Général Wahis, 53 1030 Brussels, Belgium**

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| 10000384931-PA-NA-IND Rev 2.0 | PRJC-521018-2015-MSL-IND | 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 fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- 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.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

# Conformity declaration and marking of product

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

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**

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

Certificate No.:
10000428353-PA-NA-IND Rev 2.0

Project No.:
PRJC-521018-2015-MSL-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 | 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.<br><br>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.<br><br>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).<br><br>Surgi-ORC® is sterilized by Gamma Irradiation. | | |

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

| Nr. | Numărul de catalog (referință)* | Denumire generică (denumirea dispozitivului) | Denumire comercială (brand)* | Modelul | Cod GMDN* |
|---|---|---|---|---|---|
| 1 | SOO-0214 | Membrană hemostatică | SURGI-ORC | Original / Standard, 2in x 14in (5.1cm x 35.6cm) | 38771 |
| 2 | SOO-0408 | Membrană hemostatică | SURGI-ORC | Original / Standard, 4in x 8in (10.2cm x 20.3cm) | 38771 |
| 3 | SOO-0203 | Membrană hemostatică | SURGI-ORC | Original / Standard, 2in x 3in (5.1cm x 7.6cm) | 38771 |
| 4 | SOO-502 | Membrană hemostatică | SURGI-ORC | Original / Standard, 0.5in x 2in (1.3cm x 5.1cm) | 38771 |
| 5 | SOO-0102 | Membrană hemostatică | SURGI-ORC | Original / Standard, 1in x 2in (2.5cm x 5.1cm) | 38771 |
| 6 | SOO-0304 | Membrană hemostatică | SURGI-ORC | Original / Standard, 3in x 4in (7.6cm x 10.1cm) | 38771 |
| 7 | SOO-0205 | Membrană hemostatică | SURGI-ORC | Original / Standard, 2in x 5in (5.1cm x 12.7cm) | 38771 |
| 8 | SOO-0101 | Membrană hemostatică | SURGI-ORC | Original / Standard, 1in x 1in (2.5cm x 2.5cm) | 38771 |
| 9 | SOO-66 | Membrană hemostatică | SURGI-ORC | Original / Standard, 0.6in x 0.6in (1.5cm x 1.5cm) | 38771 |
| 10 | SOK-0203 | Membrană hemostatică | SURGI-ORC | Impletit, 2in x 3in (5.1cm x 7.6cm) | 38771 |
| 11 | SOK-0304 | Membrană hemostatică | SURGI-ORC | Impletit, 3in x 4in (7.6cm x 10.1cm) | 38771 |
| 12 | SOK-0609 | Membrană hemostatică | SURGI-ORC | Impletit, 6in x 9in (15.2cm x 22.9cm) | 38771 |
| 13 | SOK-0101 | Membrană hemostatică | SURGI-ORC | Impletit, 1in x 1in (2.5cm x 2.5cm) | 38771 |
| 14 | SOK-0103 | Membrană hemostatică | SURGI-ORC | Impletit, 1in x 3in (2.5cm x 7.6cm) | 38771 |
| 15 | SOK-0135 | Membrană hemostatică | SURGI-ORC | Impletit, 1in x 3.5in (2.5cm x 8.9cm) | 38771 |
| 16 | SOK-0102 | Membrană hemostatică | SURGI-ORC | Impletit, 1in x 2in (2.5cm x 5.1cm) | 38771 |

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| 17 | SOK-0204 | Membrană hemostatică | SURGI-ORC | Impletit, 2in x 4in (5.1cm x 10.2cm) | 38771 |
| 18 | SOK-0404 | Membrană hemostatică | SURGI-ORC | Impletit, 4in x 4in (10.2cm x 10.2cm) | 38771 |
| 19 | SOK-5608 | Membrană hemostatică | SURGI-ORC | Impletit, 5.6in x 8in (14.2cm x 20.3cm) | 38771 |
| 20 | SOF-0102 | Membrană hemostatică | SURGI-ORC | Fibrila, 1in x 2in (2.5cm x 5.1cm) | 38771 |
| 21 | SOF-0204 | Membrană hemostatică | SURGI-ORC | Fibrila, 2in x 4in (5.1cm x 10.2cm) | 38771 |
| 22 | SOF-0404 | Membrană hemostatică | SURGI-ORC | Fibrila, 4in x 4in (10.2cm x 10.2cm) | 38771 |
| 23 | SOF-0203 | Membrană hemostatică | SURGI-ORC | Fibrila, 2in x 3in (5.1cm x 7.6cm) | 38771 |
| 24 | SOF-0304 | Membrană hemostatică | SURGI-ORC | Fibrila, 3in x 4in (7.6cm x 10.1cm) | 38771 |
| 25 | SOF-0202 | Membrană hemostatică | SURGI-ORC | Fibrila, 2in x 2in (5.1cm x 5.1cm) | 38771 |
| 26 | SOF-0101 | Membrană hemostatică | SURGI-ORC | Fibrila, 1in x 1in (2.5cm x 2.5cm) | 38771 |
| 27 | SON-0102 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 1in x 2in (2.5cm x 5.1cm) | 38771 |
| 28 | SON-0204 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 2in x 4in (5.1cm x 10.2cm) | 38771 |
| 29 | SON-0404 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 4in x 4in (10.2cm x 10.2cm) | 38771 |
| 30 | SON-0203 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 2in x 3in (5.1cm x 7.6cm) | 38771 |
| 31 | SON-0304 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 3in x 4in (7.6cm x 10.1cm) | 38771 |
| 32 | SON-0202 | Membrană hemostatică | SURGI-ORC | Nețesut / Zapada, 2in x 2in (5.1cm x 5.1cm) | 38771 |