

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
240230-2017-CE-BRA-NA-PS Rev. 2.0

Project No.:
PRJC-506085-2014-MSL-BRA

Valid Until:
27 May 2024

This is to certify that the quality system of:

MEDICONE PROJETOS E SOLUÇÕES PARA A INDÚSTRIA E SAUDE LTDA.

Av. das Industrias, 1585, 94930-230 Cachoeirinha, Brazil.

For design, production and final product inspection/testing of:
**STERILE UROLOGICAL IMPLANT AND STERILE
INTRAGASTRIC IMPLANT**

Has been assessed with respect to:
**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING 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, 16 October 2020

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

Cathrine Wisbech

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



Certificate No.:
240230-2017-CE-BRA-NA-PS Rev02

Project No.:
PRJC-506085-2014-MSL-BRA

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 | Revision of certificate due to transition process to Presafe NB 2460. Previous certificate was 172192-2015-CE-BRA-NA, Rev. 2.0. New European Representative. | 2017-07-27 |
| 1.0 | Scope Reduction of Testicular Implant. | 2020-02-05 |
| 2.0 | Recertification | 2020-10-16 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|----------------------|------------------------------|-------|
| INTRAGASTRIC IMPLANT | STERILE INTRAGASTRIC BALLOON | IIb |
| UROLOGIC IMPLANT | STERILE PENILE PROSTHESIS | IIb |

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

| Site Name | Address |
|---|---|
| MEDICONE PROJETOS E SOLUCÖES PARA A INDÚSTRIA E SAUDE LTDA. | Av. das Industrias, 1585, 94930-230 Cachoeirinha, Brazil. |

EU Representative

Cinterqual - Soluções de Comércio Internacional Ltda.
Fran Pacheco, 220, 2º - 2900-374 - Setúbal - Portugal

Certificate No.:
240230-2017-CE-BRA-NA-PS Rev02

Project No.:
PRJC-506085-2014-MSL-BRA

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 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