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 SOLUCÕES 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

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 SOLUCÕES 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

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

APPENDIX TO EC CERTIFICATE

Certificate no.:
240230-2017-CE-BRA-NA-PS Rev.2

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
MEDICONE PROJETOS E SOLUCÕES PARA A INDUSTRIA E A SAUDE LTDA

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Update of EU representative Address, replacing the one stated on the certificate, has been accepted.

EU Representative
Cinterqual-Soluções de Comércio Internacional,Lda Av. Defensores de Chaves, 4. Escritório Idea Spaces 1000-117. Lisboa – Portugal

Voluntary scope reduction for product UROLOGIC IMPLANT - STERILE PENILE PROSTHESIS.

Products covered by this Certificate: (replaces information on certificate)		
Product Description	**Product Name**	**Class**
INTRAGASTRIC IMPLANT	STERILE INTRAGASTRIC BALLOON 94601 – Intragastric Balloon Sterile	IIb

Place and date:
Høvik, 19 January 2023

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

Appendix History -		
Revision	**Description**	**Issued Date**
0	- Issuing Appendix of Certificate to include the commercial names/codes of products certified MDD. - Admin change: removal of “Norwegian Accreditation”.	16 December 2021
1	Voluntary Reduction of Scope and Update of EC/REP Address Change.	19 January 2023