

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 SOLUCÖES 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	IIb
	94601 – Intragastric Balloon Sterile	

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

