

EC No 1434-MDD-248/2019 Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

TELIC S.A.U. Polígono Industrial Can Barri C/ Moli d'en Barri, 7-9 Bigues i Riells, Barcelona 08415 SPAIN

for the design, manufacture and final inspection of medical devices, class: Class I(s)

Light handle cover, single-use, sterile; coupling gel, sterile

Products list in attachments: 1

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.04.2019 to 26.08.2022

The date of issue of the Certificate: 26.04.2019

C E 1434

Application No: 733/2019. Module H2/3/4/5 Mgr Anna Wyroba Vice-President



Certificate No. 1434-MDD-248/2019 Issued under the Contract No. MD-90/2019 Bears the PCBC hologram Warszawa, 26/04/2019



ANNEX 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-MDD-248/2019

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type
Coupling gel, sterile	Coupling gel, sterile	G-15E
Operating/examination/ treatment light handle cover, single-use	Operating/examination/ treatment light handle cover, single-use, sterile	LHC-01
		LHC-02
		LHC-03







Annex 1 to certificate No. 1434-MDD-248/2019 Issued under the Contract No. MD-90/2019 Bears the PCBC hologram. Warsaw, 26.04.2019