

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10316-2017-CE-KOR-NA-PS Rev. 1.0

Project No.:
PRJC-26540-2007-MSL-KOR

Valid Until:
24 November 2022

This is to certify that the quality system of:

Bio Protech Inc.

Donghwa Medical Instrument Complex, 151-3, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

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

**Electro Surgical Unit Plates and Pencils,
Pulse Oximetry Sensors (SpO2 sensors), Needle
Electrodes**

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, 18 February 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



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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	Initial certificate	24 November 2017
1.0	Change in EU Representative	18 February 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Electro Surgical Unit Plates	<ul style="list-style-type: none"> PROPLATE, Horizontal PROPLATE, Vertical 	IIb
Electro Surgical Unit Pencils	<ul style="list-style-type: none"> PROPENCIL 	IIb
Pulse Oximetry Sensors (SpO2 sensors)	<ul style="list-style-type: none"> OXI-PRO 	IIb
Needle Electrodes	<ul style="list-style-type: none"> Disposable Monopolar Needle Electrodes Disposable Concentric Needle Electrodes Disposable Hypodermic Needle Electrodes Disposable EP Needle Electrodes 	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bio Protech Inc.	Donghwa Medical Instrument Complex, 151-3, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

EU Representative

Meridius Medical Europe Ltd, Unit 3D North Point House, North Point Business Park, New Mallow Road, Cork, T23 AT2P, Ireland

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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