

EC Declaration of Conformity

Manufacturers: BIO PROTECH INC.
151-3, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

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

Name of the Device (s): Electrosurgical Unit Plates

Product / Brand code: PROPLATE

GMDN Code 58494

Classification: Class IIb

Notified Body: DNV Product Assurance AS

Notified Body Identification number: 2460

Conformity assessment route: BIO PROTECH INC. uses the following procedures for the CE-labeling of their products according the Council Directive 93/42/EEC:

Class II: EC conformity declaration according to annex IX, Rule9

This declaration of conformity is issued under the sole responsibility of BIO PROTECH INC. We hereby declare that the medical device(s) specified above meet the provision of Council Directive 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Product Assurance AS.
All supporting documentation is retained at the premises of the manufacturer.

Signature:



NAME: Ikro Park

Title: CEO

Place and date (dd.mmm.yyyy) of issue:


BIO PROTECH INC. / 19.SEP.2023

Scope of declaration of conformity

PROPLATE

No	Model Name	Type	Part Detail	Remark
1	9512F	Vertical, Non-corded	Neonatal, Split, 74x98mm, Foam	
2	9542F	Vertical, Non-corded	Adult, Split, 105x215mm, Foam	
3	9552F	Horizontal, Non-corded	Adult or Pediatric, Split, 150x120mm, Foam	
4	P9552F	Horizontal, Corded	Adult or Pediatric, Split, 150x120mm, Foam, Molding connector	

Accessory for compatibility with PROPLATE

Model	Specification	Packaging Info.	Shape
RCV300	Cable for use ARM-equipped and REM-equipped generators. Enables pad-to-patient contact quality monitoring 3m	1 each	
RCE300	Cable for use with NESSY-equipped generators 3m	1 each	