



DET NORSKE VERITAS

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

Certificate No. **4192-2007-CE-NOR** Rev. 5.0

This Certificate consists of 3 pages

This is to certify that the Quality Management 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 Electrical stimulator (TENS & EMS Unit)

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4
(Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 18 July 2012

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

Aud Løken Eiklid
Certification Manager



Notified Body No.:
0434

This Certificate is valid until:

04 July 2017

Cecilie Gudesen Torp
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.
If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall not exceed USD 300 000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



TRADUCCION SIMPLE BIO PROTECH

DET NORSKE VERITAS
EC-CERTIFICADO- SISTEMA DE ASEGURAMIENTO DE CALIDAD TOTAL

CERTIFICADO NO: 4192-2007-CE-NOR REV. 5.0
ESTE CERTIFICADO CONSISTE EN 3 PAGINAS.

Esto es para certificar que el sistema de calidad total de

BIO PROTECH INC

Donghwa medical instument complex, 151-3-, donghwagongdan-ro, munmak-eup,
wonju-si, gangwo-do, korea.

Para el diseño, produccion y la inspeccion final de producto/ o pruebas de
Platos de unidades electrogirurgicas y lapices de estimulacion electrica
(tens & ems unidad)

Han sido evaluados con el respecto a el procedimiento de evaluación de la
conformidad descritas en el artículo 11.3.a y el Anexo 11 con exclusión de la sección 4
(Módulo H), de la Directiva 93/42 / CEE del Consejo relativa Medica Consejo!
Dispositivos, según enmendada, y cumple.

Lugar y fecha
Hovik 18 de julio de 2012

Este certificado es valido hasta
04 de julio de 2017