EC CERTIFICATE

Certificate No 1493/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II of the Directive 93/42/EEC and its revised version, we hereby certify that:

BIONEN SAS DI BARBARA NENCIONI & C

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

manages in the factory of:

50127 FIRENZE (FI) - VIA P. PETROCCHI 42/1 (ITA) - Italy

a full quality assurance system ensuring the conformity of the following products:

Concentric needle electrodes, sterile and non sterile
Type ref. Codes as "Doc. 042 Rev. E del 26/10/2011"

Monopolar/sub dermal needle electrodes, sterile and non sterile
Type ref. Codes as "Doc. 042 Rev. E del 26/10/2011"

Nerve and muscle stimulating bridge
Type ref. P/N 0039.X11

Pressure Biofeedback
Type ref. P/N 0032.001

Accessories for manometry
Type ref. CAPILLARY cod. 0042.01X

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).

Reference to IMQ files Nos: COMEDCONMHDM110048419-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2012-01-23

IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2017-01-22 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

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Rea MI 1595884 - Registro Imprese MI 12898410159 - C.F./P.I.: 12898410159 - Capitale sociale 4.000.000 euro.