

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

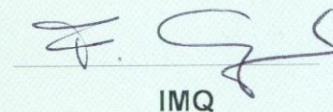
with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing).

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