

EC Certificate

EC Directive 93/42/EEC Annex V.3 Production Quality Assurance Medical Devices

Registration No.:

DD 60100071 0001

Report No.:

28107258 001

Manufacturer:

Registered Headquarter

Ionclinics & Deionic S.L. C/ Ausias March, 8.

46250 L'Alcudia (Valencia) - Spain

Scope:

EPTE SYSTEM (Percutaneous Therapeutic Electrolysis)

Model: EPTE V01

Date of Expiry: 23/02/2020

The Notified Body hereby declares that the requirements of annex V of the Directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned Directive and can be used in conjunction with the conformity declaration issued by the Manufacturer.

Pogliano Milanese (MI)

24/02/2015

B. Tuzza Tuyknamand III

Notified

TÜV Rheinland Italia S.r.I. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI) Accreditated by Ministero della Salute and by Ministero dello Sviluppo Economico with decree of January 09th, 2013 (G.U. n. 32 February 07th 2013)

Notified under No. 1936 to the EC Commission

CE

The CE marking may be used if all relevant and effective EC Directives are complied with

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