EC Certificate Full Quality Assurance System: Certificate ES12/11393

The management system of

APEIRON MEDICAL, S.L

Av. del Baró de Càrcer 48, 7F
46001 Valencia. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile single use electrosurgical device: COOLINSIDE, for haemostatic sealing, coagulation, and cut of soft tissues.

Equipo electroquirúrgico estéril de un solo uso: COOLINSIDE, para el sellado hemostático, la coagulación y el corte de tejidos blandos.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 11 May 2016 until 2 February 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 November 2017
Issue 3. Certified since 3 February 2012

Certification is based on reports numbered ES/MAD 158930

Authorised by

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