EC Certificate Full Quality Assurance System: Certificate ES07/71174

The management system of

GEM-MED, S.L.

C/ Cartagena 243, 1º - Oficina 6
08025 Barcelona. España

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

Portable electrocardiograph Gem-Heart One/One+.

Electrocardiógrafos portátiles Gem-Heart One/One+.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 12 March 2013 until 10 February 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 February 2016
Issue 4. Certified since 10 February 2007

Certification is based on reports numbered ES/MAD 69409

Authorised by

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