EC Certificate Full Quality Assurance System: TW15/10202

The management system of

ACME PORTABLE CORPORATION

5F., No.25, Wuquan 3rd Rd., Wugu Dist.,
New Taipei City 248, Taiwan R.O.C.

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 23 December 2016 until 20 February 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 December 2017
Issue 3. Certified since 20 February 2015

Certification is based on reports numbered TW/TPE 606581)

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
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SGS CE 02 0315 M2

ACME PORTABLE CORPORATION

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 3

Detailed scope

1.12 lead ECG Recorder (Model: QED2000)

2.Upper Arm Automatic Blood Pressure Monitor with AFib (Atrial Fibrillation) detecting funciton (Model: BPG-8000)

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

Additional facilities

No. 1428, Xiang Jiang Road, Suzhou New District, Suzhou City 215129, Jiangsu Province, China