I.E.M. GmbH - Cockerillstraße 69 - D-52222 Stolberg

DIN EN ISO 9001, 13485, CMDCAS

I.E.M. Industrielle Entwicklung Medizintechnik und Vertriebsgesellschaft mbH

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Certificate of Equivalence

We, the company I.E.M. GmbH,
Cockerillstr. 69
D-52222 Stolberg
Germany

declare in our own responsibility, that the device

ambulatory, non-invasive blood pressure monitor

AMEDTEC ECG Pro Holter-RR

of device class IIa

is manufactured to fulfill all applicable requirements of the Medical Device Directive MDD 93/42 EEC, Annex I from 1993.06.14, as far as they are under our responsibility. The device differs from our own CE-marked device ***Mobil-O-Graph New Generation***® with regard to the printed logos on the housing and type label only. The devices are functionally and technically identical.
All applicable tests according to EN 1060-1, EN 1060-3, EN 1060-4, EN ISO 10993-1, EN ISO 60601-1, EN ISO 60601-1-2 and EN 60601-2-30 have successfully been performed by I.E.M.
All applicable designs and developments have been performed according to EN 980, EN ISO 14971, EN ISO 60601-1-4, and EN ISO 60601-1-6.
All test reports are valid for both devices, *Mobil-O-Graph NG*® and *ECG Pro*.

I.E.M. GmbH

Uwe Korth
QM / Regulatory Affairs

23.12.2011

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