



EC DECLARATION OF CONFORMITY

Manufacturer: BeiJing Choice Electronic Technology CO., LTD.

Address: Bailangyuan Building B1127, Fuxing Road A36, Beijing,
P.R.CHINA

European representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eifflstrasse 80, 20537 Hamburg Germany

Product: Handheld ECG Monitor

Model Code: MD100A; MD100B

Classification: Class II a by Rule 10 of Annex IX, MDD93/42/ECC

Conformity of assessment route: Annex II . 3, MDD93/42/ECC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All Supporting documentation are retained at the premises of the manufacturer.

Directives

General applicable directives:

Medical Device Directive: Council Directive 93/42/ECC of 14june 1993 concerning medical devices (MDD93/42/ECC).

Standards:

Harmonized Standards (published in the Official journal of the European Communities) applicable to this product are:

ISO13485: 2003, ISO14971: 2000, ISO10993-1: 2003, IEC60601-1: 1988, /A1: 1990 , /A2 : 1995, EN60601-1-2 : 2000, IEC 60601-1-4:1996/A1:1999, IEC60601-2-47: 2001, EN980: 2003, EN1041: 1998.

Notified Body: TUV SUD PRODUCT SERVICE GMBH

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