EC Certificate Full Quality Assurance System: KR07/71481

The management system of

HuBDIC CO.,LTD.

301, 191-1, Anyang-dong, Manan-gu, Anyang-si, Gyeonggi-do, Korea

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 22 September 2017 until 28 March 2021
And remains valid subject to satisfactory surveillance audits.
Re certification audit due before 12 March 2019
Issue 24. Certified since 28 March 2007

Certification is based on reports numbered WW/PCI 216328

Authorised by

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HuBDIC CO.,LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 24

Detailed scope

Infrared ear thermometers (Model: TB-100, NET-100);

Infrared forehead thermometers (Model: FS-100, FS-201, FS-300, FS-301, FS-700, HFS-900, HFS-1000, HFS-700, HFS800/800B);

Blood pressure monitors (Model: BP-400, HBP-100, HBP-200, HBP-2000, HBP-3000);

Infrared ear and forehead thermometer (Model: TET-200, TET-201) ;

Nasal Aspirator (Model : HNA-100).

Transcutaneous electrical nerve stimulators (Model : HMB-1000, HMB-100)

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