

EC Certificate Full Quality Assurance System: Certificate 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

**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);
Blood pressure monitors (Model: BP-400, HBP-100, HBP-200, HBP-2000, HBP-3000);
Infrared ear and forehead thermometer (Model: TET-200, TET-201).**

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.

This certificate is valid from 18 September 2016 until 28 March 2021 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 12 March 2019
Issue 21. Certified since 28 March 2007

Certification is based on reports numbered WW/PCI 216328

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Certificate KR0771482

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

ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Design, Development, and Manufacture of infrared ear thermometers,
infrared forehead thermometers, blood pressure monitors,
transcutaneous electrical nerve stimulators, blood glucose measuring
systems for selftesting and blood pressure monitoring/blood glucose
measuring systems for selftesting.**

This certificate is valid from 7 September 2016 until 28 March 2019 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 12 March 2019
Issue 10. Certified since 28 March 2007

Authorised by



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Certificate KR16/02665

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

ISO 9001:2008

For the following activities

Design, Development, and Manufacture of infrared ear thermometers, infrared forehead thermometers, blood pressure monitors, transcutaneous electrical nerve stimulators, blood glucose measuring systems for selftesting and blood pressure monitoring/blood glucose measuring systems for selftesting.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 7 September 2016 until 14 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 September 2018
Issue 1. Certified since 7 September 2016

Authorised by

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