

EC Certificate Full Quality Assurance System: Certificate KR10/01443

The management system of

## HANSUNG MEDICAL Corporation

81, Seoheung 1-gil, Mokcheon-eup, dongnam-gu, Cheonan-si, Chungcheongnam-do, 330-842 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

Steam Sterilizer for invasive and non-invasive medical devices (Model: HTA- 50V, HTA-30V\_Type of Sterilization Cycle B).

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 26 September 2016 until 29 April 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 April 2019

Issue 7. Certified since 29 April 2010

Certification is based on reports numbered KR/SEL Y-PC/10232

Authorised by

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