EC Certificate Full Quality Assurance System: KR15/02480

The management system of

HT Co., Ltd

(HQ & 1st Factory) Heungdeok, Jungangno 120 U-Tower No. 1313,
Giheung-gu, Yongin-si, Gyeonggi-do, Korea 446-908

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 21 July 2015 until 21 July 2020 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 February 2018
Issue 1. Certified since 21 July 2015

Certification is based on reports numbered Y-PC/15401

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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HT Co., Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Non-sterile Orthodontic Ceramic Bracket (MISO, MISO mini, Cross C, IDEAL);

Non-sterile Orthodontic Resin Bracket (CUTE, ETS);

Non-sterile Orthodontic Metal Bracket (CROSS-M)

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

Additional facilities

(2nd Factory) Singuro 72-7, Gilheung-gu, Yongin-si, Gyeonggi-do, Korea 446-594