

EC Certificate Full Quality Assurance System: Certificate CN16/30458

The management system of

TELEFIELD MEDICAL IMAGING LIMITED

Flat D, 2/F., Valiant Industrial Centre, 2-12 Au Pui Wan Street, Fo Tan,
New Territories, Hong Kong, P.R. China

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

Radiation-free 3D Ultrasound Scoliosis Assessment System (Model: SCN801)

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 27 June 2016 until 26 June 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 January 2019
Issue 1. Certified since 27 June 2016

Certification is based on reports numbered CN/SZX 49926

Authorised by

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