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EC Certificate Full Quality Assurance System: Certificate CN19/41097

The management system of

Double Medical Technology Inc.

No. 18, Shanbianhong East Road, Haicang District, Xiamen, 361026, 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

Electrical Bone Drill and Bone Saw
Sterile Percutaneous Kyphoplasty (PKP) System
Sterile and non-sterile medical devices (Metal Intramedullary Nail System, Metal Bone Pin, Metal Locking Bone Plate System, Metal Bone Screw and Metal Spinal System)

Sterility aspects only Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.
Sterile External Fixators.

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 22 April 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 01 July 2013
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CN/XMN 6103MD

Authorised by

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