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## Certificate

No. Q5 102159 0001 Rev. 02

**Holder of Certificate:** 

**Double Medical Technology Inc.** 

No. 18, Shanbianhong East Road

Haicang District

361026 Xiamen, Fujian

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and

**Distribution of Orthopaedic Surgical** 

Instruments, External Fixators, Bone Plates, Bone Screws, Bone Pin, Intramedullary Nail System, Spinal Bone Plate System, Spinal System, Spinal CAGE/Mesh, Orthopaedic Cable System, Joint Prosthesis, Mini Type Metallic Bone Plates & Screws System,

**Titanium Mesh & Screw System for Cranium** 

**Defect Reparation, Titanium Sternal** 

Fixation System, Soft Tissue Injury Repair

and Reconstruction System

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

GZ1939703

Valid from:

2020-01-17

Valid until:

2022-01-06

Date,

2020-01-17

Christoph Dicks

Head of Certification/Notified Body



## Certificate

No. Q5 102159 0001 Rev. 02

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Double Medical Technology Inc.

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

Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA

Double Medical Technology Inc.

Section J, F/1 of Workshop, No. 1-3, Dingshan Road, Haicang District, 361026 Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA