



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147800 0001

Report No.: 15096009 007

Manufacturer: Ningbo Mingtai Medical Instrument
Co., Ltd.
Yunzhen Road, Industrial Zone
Yunlong Town, Yinzhou
315137 Ningbo City
P.R. China

Products: Steam Sterilizers
Replaces Approval, Registration No.: HD 60112962 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-17

Date: 2020-04-17

Notified Body



Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Ningbo Mingtai Medical Instrument
Co., Ltd.**
Yunzhen Road, Industrial Zone
Yunlong Town, Yinzhou
315137 Ningbo City
China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and
Distribution of Steam Sterilizers**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-13
Certificate Registration No.: SX 60130306 0001
An audit was performed. Report No.: 15096009 003
This Certificate is valid until: 2021-08-17

Certification Body



Date 2018-12-13



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