# Certificate

TÜVRheinland®

**Quality Management System**
**EN ISO 13485:2016**

| | |
|---|---|
| Registration No.: | SX 2183303-1 |
| Organization: | Hangzhou Headway Medical Equipment Co., Ltd.<br>No.1859, Wenju Street, Fuchun Street,<br>Fuyang District, Hangzhou City,<br>311400 Zhejiang<br>P.R. China |
| Scope: | Manufacture and Distribution of Orthodontic Metal Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Orthodontic Crimpable Hooks, Orthodontic Power Hooks, Orthodontic Lingual Buttons, Orthodontic Lingual Sheaths, Orthodontic Archwires, Orthodontic Elastomeric Auxiliaries, Orthodontic Ceramic Brackets |

Digitally signed by Romanenco Alexandru
Date: 2023.11.21 16:16:52 EET
Reason: MoldSign Signature
Location: Moldova

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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|---|---|
| Report No.: | 244311414-200 |
| Effective date: | 2021-09-23 |
| Expiry date: | 2024-08-13 |
| Issue date: | 2021-09-23 |

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

**Registration No.:** DD 60131504 0001

**Report No.:** 15086010 004

**Manufacturer:**
Hangzhou Headway Medical
Equipment Co., Ltd.
No. 1859, Wenju Street, Fuchun Street
Fuyang District
Hangzhou City
311400 Zhejiang
China

**Products:** Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60103997 0001

**Expiry Date:** 2023-08-27

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2018-09-17

**Date:** 2018-09-17

Notified Body

X. Ren

**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.

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Doc. 1/1, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** DD 60131504 0001
**Report No.:** 15086010 004

**Manufacturer:**
Hangzhou Headway Medical Equipment Co., Ltd.
No. 1859, Wenju Street, Fuchun Street
Fuyang District
Hangzhou City
311400 Zhejiang
China

Products:

- Orthodontic Metal Brackets
- Orthodontic Bands
- Orthodontic Buccal Tubes
- Orthodontic Crimpable Hooks
- Orthodontic Power Hooks
- Orthodontic Lingual Buttons
- Orthodontic Lingual Sheaths
- Orthodontic Archwires
- Orthodontic Elastomeric Auxiliaries
- Orthodontic Ceramic Brackets

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-09-17

X. Ren

TÜVRheinland®
Precisely Right.

2023-08-14

**To Whom It May Concern**

TÜV Rheinland (Shanghai) Co., Ltd., China. confirms that the manufacturer Hangzhou Headway Medical Equipment Co., Ltd. has lodged an application for conformity assessment based on REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III (Quality Management System).

The transition timelines according to (EU) 2023/607 are shown below:
• 26 May 2026 for Class III custom-made implantable devices
• 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
• 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
• 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Concerning MDD Certificate No.: DD 60131504 0001, expiry date: 2023-08-27, TÜV Rheinland (Shanghai) Co., Ltd. will continue to do MDD surveillance audit for Hangzhou Headway Medical Equipment Co., Ltd.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Tony Chen

Mr. Tony Chen
Location Field Manager
Greater China，Medical Services

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