

*Hangzhou Jinlin Medical Appliances Co., Ltd.
M14-3-4 Hangzhou Economic & Technological
Development Zone,
310018 Hangzhou, Zhejiang
China*

Your ref.
Our ref. MED/22-7491855
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 2023-12-19

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (dated 2023-02-07) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Hangzhou Jinlin Medical Appliances Co., Ltd.
M14-3-4 Hangzhou Economic & Technological Development Zone,
310018 Hangzhou, Zhejiang
China
SRN Number: CN-MF-000012391

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2

identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (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)

On behalf of the Notified Body,



Xiaoli Ren
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Tracheostomy Tubes - with cuff - without cuff - with suction lumen	Class IIb excluding Class IIb implantable non-WET device	N/A	Certificate #HD 60140292 0001; NB 0197
Tracheal Tubes - with cuff - without cuff - with cuff and suction lumen - stylet	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Stopcocks -Three-way stopcock -Three-way stopcock with extension; -Three-way stopcock with pressure monitoring line; -Three-way stopcock manifold; -Two-way stopcock; -Extension tubes - for	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
infusion/for pressure monitoring / for micro-infusion Extension Tubes ; -CVP manometer			
Suction Catheters -Suction catheter -Closed suction catheter	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Oxygen Masks -Simple oxygen mask -Venturi mask -Oxygen mask with reservoir bag -Aerosol mask -Tracheostomy masks -Oxygen connecting tube	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Nasal Oxygen Cannulas -with sampling cannula -without sampling cannula -Sampling tube	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Nebulizers -with mask -with mouthpiece -with mask and mouthpiece -Nebulizer jar	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Yankauer suction Handles -with slid vent and suction tube -with vent and suction tube	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-without vent and suction tube -with slid vent -with vent -without vent -suction tube			
Extension Tubes	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Face Masks with Air Cushion -pre-inflated -adjustable	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
CPR Masks -with oxygen inlet -without oxygn inlet -One way valve	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Tracheostomy Masks	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
Breathing Systems -for anaesthesia for adult -for anaesthesia for pediatry -for ventilator for adult -for ventilator for pediatry	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197
CVP manometers	Class IIa	N/A	Certificate #HD 60140292 0001; NB 0197

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023-12-19	6145055CN01.1	Initial issue

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

Registration No.: HD 60140292 0001

Report No.: 15077208 008

Manufacturer: Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60118053 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: 2020-01-20

Date: 2020-01-20



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60140292 0001
Report No.: 15077208 008

Manufacturer: Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
P.R. China

Products:

- Tracheostomy Tubes
- Tracheal Tubes
- Stopcocks
- Suction Catheters
- Oxygen Masks
- Nasal Oxygen Cannulas
- Nebulizers
- Yankauer Suction Handles
- Extension Tubes
- Face Masks with Air Cushion
- CPR Masks
- Tracheostomy Masks
- Breathing Systems
- Disposable Anaesthesia Air Filters
- CVP Manometers

Aspects of manufacture concerned with securing
and maintaining sterile conditions:

- Laryngoscope Blades

Date: 2020-01-20

Notified Body

