DEKRA Certification B.V.

CERTIFICATION NOTICE

Number : 6145055CN	Initial date : 28 November 2023
Version : 01.1	Version date : 19 December 2023

The Certification Notice provides actual information concerning the application(s) made by the Certification holder and the product(s) covered by the Certificate(s) as well as information regarding the examination and assessment activities performed by the Certification Body related to the performed Conformity Assessment Procedure(s) and the reference to the relevant documentation.

1 CERTIFICATION HOLDER

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

2 APPLICATION(S)

The application(s) made by the Certification holder under the provisions of below-mentioned standard(s) conform(s) to the applicable provisions of the EC-Directive/regulation(s), ISO standards and/or other regulations and include(s) the documentation and the relevant undertakings and/or statements required:

- **QMS standards:** EN ISO 13485:2016 (RvA).

3 CE CERTIFICATION STRUCTURE

To cover all products included in the application(s), the following scope(s) for the CE-certificates are defined:

NA

4 QUALITY SYSTEM STRUCTURE

The assessment of the applied Quality System of the certification holder is primarily covered by the assessment based on the standards identified in the table below.

QMS certificates issued by DEKRA Certification:

Certificate number	Scope of certificate	QS Standard(s)
6145055	Design and Development, Manufacture and Distribution of Tracheostomy Tubes, Tracheal Tubes, Suction Catheters, Nebulizers, Breathing Systems, Nasal Oxygen Cannulas, Oxygen Masks, Tracheostomy masks, Face Masks with Air Cushion, CPR Masks, Oxygen Connecting Tubes, Yankauer Suction Handles, Stopcocks, Extension Tubes, CVP Manometers, Manually Powered Suction Equipment for the area of respiratory care and for administration, channelling and removal of substances	EN ISO 13485:2016

Exclusions:	NA
Non-Applications:	7.5.3 installation activities; 7.5.4 servicing activities; 7.5.9.2 particular requirements for implantable medical devices

5 ADDITIONAL LOCATION(S)

The relevant additional sites covered by a Quality System under responsibility of the Certification holder are identified in the table below.

Location	Certification scope / Activity
No.18 Jinxiu Road, Xuancheng Economic and Technological Development Zone, Xuancheng Anhui, China	Manufacture of Suction Catheters, Nebulizers, Breathing Systems, Nasal Oxygen Cannulas, Oxygen Masks, Tracheostomy masks, Oxygen Connecting Tubes for the area of respiratory care and for administration, channelling and removal of substances

6 SUBCONTRACTED REGULATORY REPRESENTATION

The Certification Holder’s subcontracted regulatory representation, covered by a QA/RA agreement, is identified in the table below.

Company name / city / country	Type of service to Certification holder
Shanghai international Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany	EU Authorized representative

7 SUBCONTRACTOR(S) / OUTSOURCING

The critical subcontractors performing processes, which results are not or cannot be verified by the Certification holder and/or the critical contractors to which relevant processes have been outsourced are identified in the table below:

N/A

8 EVALUATION OF TECHNICAL DOCUMENTATION

The examination and assessment of the Design Dossier(s), verification or examination/assessment of the technical documentation and/or the verification of manufactured products / batches are identified in the table below.

N/A

9 EVALUATION OF QUALITY MANAGEMENT SYSTEM

The applied Quality System has been assessed to determine whether this Quality System complies with the applicable requirements of the EC-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice. This is described in the audit report(s) mentioned in the table below.

Activity (audit/substantial change) brief description	**Reference to client's MAF or NoC or n/a**	**Conformity Assessment Route**	**Applies to following certificate number(s) and CN version**	**Report or review letter (+ date of approval)**
ISO stage 1 audit (May 2023)	MAF (signed 21 Nov. 2022)	-/-	6145055 6145055CN01	6145055-AR01-R0 (approved on 28 November 2023)
ISO stage 2 and initial MDR audit (June 2023)	MAF (signed 21 Nov. 2022)	MDR, Annex IX	6145055 6145055CN01	6145055-AR02-R0 6145055-NCR02-R0 (approved on 28 November 2023)

DEKRA Certification has determined by examination and assessment that the applied Quality System(s) comply with the relevant requirements in accordance with the applied conformity assessment procedure(s) of the EC-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice.

10 CONCLUSION

DEKRA Certification declares, based on the results of the examination and assessment activities performed, that the applied Conformity Assessment Procedures are executed by the Certification holder in accordance with the provisions of the EC-Directive/regulation, ISO standards and/or other regulations.

With regards to CE certification, the compliance of the products concerned with the Essential Requirements/GSPR (Annex I) of the EC-Directive/regulation remain, according to the provisions of this Directive/regulation, at all times the full responsibility of the Certification holder.

The following certificates will be issued under the conditions of the signed certification agreement CA-23-7491855:

In the case of expired MDD certificates HD 60140292 0001 (as listed in the table below) but which is not subject to surveillance by DEKRA Certification per Regulation (EU) 2023/607 amending Regulations (EU) 2017/745, this is under the conditions of the signed Manufacturer's Declaration, date 2023-11-30.

MDD

Certificate number	Initial date	Renewal date	Revision date*	Expiry date
HD 60140292 0001 (issued by TÜV Rheinland LGA Products GmbH, NB0197)	-	20 January 2020	-	26 May 2024

ISO

Certificate number	Standard	Initial date	Effective date*	Expiry date
6145055	EN ISO 13485:2016	1 December 2023	1 December 2023	1 December 2028

*** C for certificate, A for addendum**

The right to use the DEKRA Certification Identification Number **0344**, as stated in the relevant Certificate(s) and under the conditions of said Agreement, only applies to the product(s) covered by this Certification Notice.

19 December 2023

Signature of Certification Manager

Date

DEKRA Certification B.V, Arnhem, The Netherlands