Number: 6122159CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Haiyan Kangyuan Medical Instrument Co., Ltd.

Songpodong Road, Shendang Town
314311, Haiyan, Zhejiang
China
SRN ID.: CN-MF-000001532

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6122159CN

Authorized Representative:
Eunitor GmbH
Kennedydamm 5 40476 Düsseldorf Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Principal Certification Manager

First Issued: **1 February 2023** Date: **19 July 2023** Expiry date**: 1 February 2028**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable devices for anaesthesia, emergency and intensive care (MDN1201, Class IIa)
Device Name: - Endotracheal Tubes for Single Use - Sterile Suction Catheters for Single Use - Oxygen Masks for Single Use - Nasal Oxygen Cannulas for Single Use - Guedel Airways for Single Use - Laryngeal Mask Airways - Anesthesia Masks for Single Use - Breathing Filters for Single Use - Breathing Circuits for Single Use

URETERAL CATHETERS WITH BALLOON – OTHER (U020299, Class IIb)	
Device Name: Urinary Catheters for Single Use (Foley)	*Intended Purpose: The product is intended to continuous urinate and douche urinary bladder by inserting into urinary bladder though urethra.*

Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	**1 February 2023**	6122159CN01	first issue
1	**19 July 2023**	6122159CN02	Revised

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