EU Declaration of Conformity

MANUFACTURER (name and address):	Haiyan Kangyuan Medical Instrument Co.,Ltd. Songpodong Road Shendang Town,Haiyan, Zhejiang 314311, China.
SRN:	CN-MF-000001532
AUTHORIZED REPRESENTATIVE (name and address):	Eunitor GmbH Kennedydamm 5 40476 Düsseldorf Germany
SRN:	DE-AR-000005081

PRODUCTS:

Product Name	Product number / catalogue number	Basic UDI-DI	Description	Classification
Urinary Catheters for Single Use (Foley)	See appendix 1	6948097001DNGGN	The product is intended to continuous urinate and douche urinary bladder by inserting into urinary bladder though urethra.	Class IIb; Rule 5

CONFORMITY ASSESSMENT ROUTE: MDR 2017/745 Annex IX

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:	Applied standards are listed in the General Safety and Performance Requirements Checklist
NOTIFIED BODY:	DEKRA Certification B.V. Meander 1051/6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands Notified body number: 0344
EU CERTIFICATE:	6122159CE01
EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE:	N/A

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Urinary Catheters for Single Use (Foley)	KY-01	19 July 2023	/

Place, Date of issue: 20 July 2023
Expiry date: 1 February ,2028

SIGNATURE: Ya ling Xu

Yaling Xu
Person responsible for regulatory compliance
For and on behalf of Haiyan Kangyuan Medical Instrument Co.,Ltd.

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Appendix 1 Product number

- Product model/specification

According to the number of cavity head, it is divided into Two-Way, Three-Way

According to the balloon structure, it can be divided into Normal Balloon and Integral Flat Balloon

According to the tip shape is divided into Nelaton Tip and Tiemann Tip

According to whether the plug is configured, it can be divided into type with plug and type without plug.

- The specifications of urinary catheter shall be in accordance with Table 1.

Table1 Model and specification

Model	specification
Two-Way- Normal Balloon- Nelaton Tip	6Fr/8Fr/10Fr/12Fr/14Fr/16Fr/18Fr/20Fr/22Fr/24Fr/26Fr
Two-Way- Integral Flat Balloon- Nelaton Tip	
Two-Way- Normal Balloon- Tiemann Tip	
Two-Way- Integral Flat Balloon- Tiemann Tip	
Three -Way- Normal Balloon- Nelaton Tip	8Fr/10Fr/12Fr/14Fr/16Fr/18Fr/20Fr/22Fr/24Fr/26Fr

Table 2: Specifications and dimensions

Model	Specification (Fr/Ch)	OD (mm)	Color for fixed sets	The max capacity of balloon	Intended patient
Two-Way	6	2.0	Light green	1.5 mL、3mL、5mL	Pediatric
Two-Way, Three-Way	8	2.7	Light blue		
	10	3.3	Black		
	12	4.0	White	2 mL、5mL、10mL、15mL	Adult
	14	4.7	Green	2mL、5mL、10mL、15mL、20mL、30mL	
	16	5.3	Orange	2mL、5mL、10mL、15mL、20mL、30mL	
	18	6.0	Red	5mL、10mL、20mL、30mL	
	20	6.7	Yellow		
	22	7.3	Purple		
	24	8.0	Blue		
	26	8.7	Pink		

The balloon capacity label allows the range of nominal minimum and maximum balloon filling volumes to be expressed, such as 5-15 mL

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- Structure composition

Model	Specification	Structural composition	
		without plug	with plug
Two-Way	6Fr、8 Fr、10Fr	Shaft, balloon（Normal Balloon or Integral Flat Balloon）, tip（Nelaton Tip or Tiemann Tip）, drainage funnel, filling funnel, valve, fixed sets, drain hole and stylet	Add drain plug
	12Fr、14 Fr、16Fr、18Fr、20Fr、22Fr、24Fr、26Fr	Shaft, balloon（Normal Balloon or Integral Flat Balloon）, tip（Nelaton Tip or Tiemann Tip）, drainage funnel, filling funnel, valve，fixed sets，and drain hole.	Add drain plug
Three-Way	8 Fr、10Fr	Shaft, Normal balloon, Nelaton Tip, drainage funnel, filling funnel, flushing funnel, valve、fixed sets, drain hole，flushing hole，stylet	Add drain plug and flushing plug.
	12Fr、14 Fr、16Fr、18Fr、20Fr、22Fr、24Fr、26Fr	Shaft, Normal balloon, Nelaton Tip, drainage funnel, filling funnel, flushing funnel, valve、fixed sets, drain hole，flushing hole	Add drain plug and flushing plug.

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