

## 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                    | 6948097001DNNGG<br>N | The product is intended to continuous urinate and douche urinary bladder by inserting into urinary bladder through urethra. | Class IIb;<br>Rule 5 |

CONFORMITY ASSESSMENT MDR 2017/745 Annex IX  
ROUTE:

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:  
Expiry date:

20 July 2023  
1 February ,2028

SIGNATURE:



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

➤ 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<br>(Fr/Ch) | OD<br>(mm) | Color for<br>fixed sets | The max capacity of balloon     | Intended<br>patient |
|-----------------------|--------------------------|------------|-------------------------|---------------------------------|---------------------|
| Two-Way               | 6                        | 2.0        | Light green             | 1.5 mL、3mL、5mL                  | Pediatric           |
| Two-Way,<br>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、<br>20mL、30mL |                     |
|                       | 16                       | 5.3        | Orange                  | 2mL、5mL、10mL、15mL、<br>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

➤ 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. |