

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 N	The product is intended to continuous urinate and douche urinary bladder by inserting into urinary bladder through 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	/

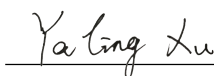
Place, Date of issue:

20 July 2023

Expiry date:

1 February 2028

SIGNATURE:



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

Appendix 1 Product number

REF.	Model	Specification(Fr/Ch)	Balloon capacity(mL)
01/01/07/12/10/GHC	Two-Way, Whistle Tip	12	10
01/01/07/14/10/GHC	Two-Way, Whistle Tip	14	10
01/01/07/16/30/GHC	Two-Way, Whistle Tip	16	30
01/01/07/18/30/GHC	Two-Way, Whistle Tip	18	30
01/01/07/20/30/GHC	Two-Way, Whistle Tip	20	30
01/01/07/22/30/GHC	Two-Way, Whistle Tip	22	30
01/01/08/12/05/GHC	Two-Way, Tiemann Tip	12	5
01/01/08/14/20/GHC	Two-Way, Tiemann Tip	14	20
01/01/08/16/30/GHC	Two-Way, Tiemann Tip	16	30
01/01/08/18/30/GHC	Two-Way, Tiemann Tip	18	30
01/01/08/20/30/GHC	Two-Way, Tiemann Tip	20	30
01/01/08/22/30/GHC	Two-Way, Tiemann Tip	22	30
01/01/08/24/30/GHC	Two-Way, Tiemann Tip	24	30
01/01/11/06/03/GHC	Two-Way, Nelaton Tip	6	3
01/01/11/08/05/GHC	Two-Way, Nelaton Tip	8	5
01/01/11/10/05/GHC	Two-Way, Nelaton Tip	10	5
01/01/11/12/10/GHC	Two-Way, Nelaton Tip	12	10
01/01/11/14/10/GHC	Two-Way, Nelaton Tip	14	10
01/01/11/16/30/GHC	Two-Way, Nelaton Tip	16	30
01/01/11/18/30/GHC	Two-Way, Nelaton Tip	18	30
01/01/11/20/30/GHC	Two-Way, Nelaton Tip	20	30
01/01/11/22/30/GHC	Two-Way, Nelaton Tip	22	30
01/01/11/24/30/GHC	Two-Way, Nelaton Tip	24	30
01/01/11/26/30/GHC	Two-Way, Nelaton Tip	26	30

01/01/25/12/05/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	12	5
01/01/25/14/05/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	14	5
01/01/25/16/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	16	10
01/01/25/18/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	18	10
01/01/25/20/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	20	10
01/01/25/22/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Transparent	22	10
01/01/26/12/05/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	12	5
01/01/26/14/05/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	14	5
01/01/26/16/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	16	10
01/01/26/18/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	18	10
01/01/26/20/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	20	10
01/01/26/22/10/GHC	Two-Way, Integral Flat Balloon, Nelaton Tip, Blue	22	10