

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
Suprapubic Catheters for Single Use	See appendix 1	6948097002KKGHP	The Suprapubic catheter is used to provide a route for suprapubic bladder drainage, when a catheter inserts into the bladder via the abdominal wall.	Class IIb; Rule 8

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
Suprapubic Catheters for Single Use	KY-02	10 April 2025	/

Place, Date of issue:

10 April 2025

Expiry date:

1 February 2028

SIGNATURE:

Yaling Xu

海盐康源医疗器械有限公司
HAIYAN KANGYUAN MEDICAL INSTRUMENT CO.,LTD.

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)
01/02/09/12/05/GHC	Two-Way, Transparent, Integral Flat Balloon	12	5
01/02/09/14/05/GHC	Two-Way, Transparent, Integral Flat Balloon	14	5
01/02/09/16/10/GHC	Two-Way, Transparent, Integral Flat Balloon	16	10
01/02/09/18/10/GHC	Two-Way, Transparent, Integral Flat Balloon	18	10
01/02/09/20/10/GHC	Two-Way, Transparent, Integral Flat Balloon	20	10
01/02/09/22/10/GHC	Two-Way, Transparent, Integral Flat Balloon	22	10
01/02/11/12/05/GHC	Two-Way, Blue, Integral Flat Balloon	12	5
01/02/11/14/05/GHC	Two-Way, Blue, Integral Flat Balloon	14	5
01/02/11/16/10/GHC	Two-Way, Blue, Integral Flat Balloon	16	10
01/02/11/18/10/GHC	Two-Way, Blue, Integral Flat Balloon	18	10
01/02/11/20/10/GHC	Two-Way, Blue, Integral Flat Balloon	20	10
01/02/11/22/10/GHC	Two-Way, Blue, Integral Flat Balloon	22	10