湖南省华芯医疗器械有限公司
Hunan Vathin Medical Instrument Co., Ltd

Declaration of Conformity

Manufacturer:	Hunan Vathin Medical Instrument Co., Ltd
Address	1/F,Building 12, 1/F Building 11, Innovation and Entrepreneurship Service Center No 9 Chuanqi West Road, Jiuhua Economic Development Zone, 411100 Xiangtan, Hunan, China
SRN	CN-MF-000002593

Products:

Product Name	Model	EMDN Code	Classification
Single-use Flexible Bronchoscope	BC-P1600、BC-P1601、BC-P1602、 BC-P1603、BC-P1604、BC-P1600-L、BC-P1601-L、BC-P1602-L、BC-P1603-L、BC-P1604-L 、BC-P16001、BC-P16011、BC-P16021、BC-P16031、BC-P16041、BC-P16001-L、BC-P16011-L、BC-P16021-L、BC-P16031-L、BC-P16041-L	Z12020802	IIa, Rule 5, Rule 10

Conformity Assessment Route:	MDR Annex IX
Basic UDI-DI	697219748BC2X
Intended Purpose	The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units,It is used for airway and bronchus examination, diagnosis and treatment.
Standards Applied:	Applied standards are listed in the Essential Requirements Checklist
Applicable Standards:	ISO 13485 Medical devices - Quality management systems ISO 14971 Medical Devices-Application of Risk Management to Medical Devices EN 15223-1 Symbols for use in the labelling of medical devices EN ISO 20417 Medical Devices-Information to be supplied by the manufacture IEC 60601-1 Medical electrical equipment-Part1: General requirements for safety IEC 60601-1-2 Medical electrical equipment-Part1: General requirements for safety IEC 60601-2-18 Medical electrical equipment-Part2: Particular requirements for the safety of endoscopic equipment IEC 62366-1 Application of usability engineering to medical device ISO 10993 Biological evaluation of medical devices ISO 11135 Sterilization of health care products ISO 11607 Packaging for terminally sterilized medical devices ISO 8600 Endoscopes — Medical endoscopes and endotherapy devices
European Authorized Representative	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Notified Body:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands
Notified body number:	0344
(EC) Certificate(s):	6079142CE01
ISO Certificate(s):	6051638

Start of CE-marking: 2025.Jan.02

We herewith declare that the above-mentioned products meet the provisions of the Medical Device Regulation EU 2017/745 for medical devices, and the Declaration of Conformity is issued under the sole responsibility of Hunan Vathin Medical Instrument Co., Ltd.. All supporting documentation is retained at the premises of the manufacturer.

Signature: 

Du Jing
PRRC(Person Responsible for Regulatory Compliance)
For and on behalf of HUNAN VATHIN MEDICAL INSTRUMENT CO., LTD.

Place, Date of issue: Xiangtan, China, 2025/01/03