

Declaration of Conformity

MANUFACTURER: Hunan Vathin Medical Instrument Co., Ltd

ADDRESS OF COMPANY: 1/F, Building 12, Innovation and Entrepreneurship Service Center, No 9 Chuanqi west road, Juhua Economic Development Zone, 411100 Xiangtan, Hunan, China

PRODUCTS:

Product Name	Model	Description	GMDN Code	Classification
Video bronchoscope system:		Flexible video bronchoscope, single-use, with a non-sterile, reusable video processor		Class IIa; Annex II, rule 5, rule 10
Single-use flexible Video Bronchoscope	BCV1-01, BCV1-02, BCV1-0M1, BCV1-0M2, BCV1-C1, BCV1-C2, BCV1-H1, BCV1-H2, BCV1-KS3-L, BCV1-K1, BCV1-K2, BCV1-M1, BCV1-M2, BCV1-O1, BCV1-O2, BCV1-S1, BCV1-S2, BCV1-U1, BCV1-U2, BCV1-W1, BCV1-W2		60963 Flexible video bronchoscope, single-use	
Digital Video Processor	DVP-A1		18034 Endoscopic video image processor	

CONFORMITY ASSESSMENT ROUTE: MDD Annex II

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 1041 Information supplied by the manufacturer of medical devices
 IEC60601-1 Medical electrical equipment-Part1: General requirements for safety
 IEC60601-1-2 Medical electrical equipment-Part1: General requirements for safety
 IEC60601-2-18 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
 IEC 62304 Medical device software – software life cycle processes

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED: Applied 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 REP: Lotus NL B.V.
ADDRESS OF EU REP: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands.

EC CERTIFICATE: 6051918CE01

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Single-use flexible Video Bronchoscope	BCV1-01, BCV1-02, BCV1-C1, BCV1-C2, BCV1-H1, BCV1-H2, BCV1-K1, BCV1-K2, BCV1-M1, BCV1-M2, BCV1-O1, BCV1-O2, BCV1-S1, BCV1-S2, BCV1-U1, BCV1-U2, BCV1-W1, BCV1-W2	29 April 2020	Batch No.:T200201 (BCV-M2)、T191105 (BCV-02)、T191204 (BCV-S2)、T191011 (BCV-W2)、T200204 (BCVC2)
Digital Video Processor	DVP-A1	29 April 2020	Batch No.:M2003001

PLACE, Xiangtan, Hunan

DATE OF ISSUE: 2022.10.18

SIGNATURE:


General Manager
For and on behalf of Hunan Vathin Medical Instrument Co., Ltd

