



**HUNAN VATHIN MEDICAL INSTRUMENT CO.,LTD**

Floor 1, Building 12 of Innovation and Entrepreneurship Service Center, No.9 West Chuanqi Road, Jiuhua Economic and Technological Development Zone, Xiangtan, Hunan Province, PRC

**DECLARATION OF CONFORMITY**

According to REGULATION(EU) 2017/745 -Article 19, Annex II and Annex III.

**Manufacturer:**

Company name:Hunan Vathin Medical Instrument Co., Ltd

Address: 1/F, Building 12, Innovation and Entrepreneurship Service Center, No.9 Chuanqi West road, Jiuhua Economic Development Zone, Xiangtan, Hunan,China

Tel:+86-21-34781226

E-mail: service@vathin.com

SRN: CN-MF-000002593

**Whose Authorized Representative:**

Name:: Lotus NL B.V.

Address: Koningin Julianaplein 10,1eVerd, 2595AA, The Hague, Netherlands.

mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Digital Video Monitor		
Model	DVM-B1、 DVM-B2		
Intend use	The equipment is specially designed to be used with medical endoscopes and other auxiliary equipment for the purposes of endoscopic diagnosis, treatment and video observation. Never use the product for any purposes other than those stated in this manual. Digital video monitor is intended for patients requiring endoscopic diagnosis or treatment.		
EMDN code	Z12020406	Basic UDI-DI	697219748*DVMB*EL
Classification and rule	Class I , Rule I	Conformity Assessment Route	Article 19, Annex II and Annex III



**Applicable Standards and CS:**

ISO 13485:2016/ISO 14971 :2019 /EN 15223-1:2016/EN 1041:2008/ IEC 60601-1-2 /IEC60601-1

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.



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

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Signed: *Lily Fei*  
Date: July 14, 2022  
Place: Hunan, China



Name of authorized signatory: Lily Fei  
Position held in the company: General Manager  
Hunan Vathin Medical Instrument Co., Ltd.

