EC Declaration of Conformity

Manufacturer:

Shenzhen HugeMed Medical Technical Development Co., Ltd
Address：416-1, 516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street,Longgang District, Shenzhen, Guangdong Province, 518115, China
Single Registration Number: CN-MF-000010895

European representative:

Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80,20537 Hamburg, Germany
Single Registration Number: DE-AR-000000001

Product name: Flexible Video Ureterorenoscope

Brand name: /

Device Nomenclature Code: Z12020709

Intended Purpose: The Flexible Video Ureterorenoscope consists of two handles (HU Vision), disposable Flexible Ureterorenoscope HU30 and reusable Flexible Ureteroscope HU32, which to be introduced within the urinary tract and video processor (Hvision) HUV-01 for clinical image processing. The device is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Basic UDI-DI:

HU Vision (HU30): 69704625480008M

HU Vision (HU32): 69704625480018P

Hvision (HUV-01): 69704625480028R

Product: See Annex 1

Applicable Standard(s): See Annex 2

Classification:

Hvision (HUV-01)：According to Annex VIII, rule 10 and rule 11 of the Regulation (EU) 2017/745 (MDR), Hvision (HUV-01) is in class IIa;

HU vision (HU30, HU32): According to Annex VIII, rule 5 and rule 10 of the Regulation (EU) 2017/745 (MDR), Hvision (HU30, HU32) is in class IIa.

Conformity assessment route: Annex IX, Regulation (EU) 2017/745 (MDR) Ch.I and III

We hereby declare that the above mentioned product meet the provisions of the Regulation (EU) 2017/745 (MDR) for medical devices. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances are incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body 2797, BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

Notify Body: BSI Group Netherlands BV

CE 2797

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No.: MDR736670	2021-12-06	2022-03-16	2026-12-05

The EU Declaration of Conformity is issued under sole responsibility of the Shenzhen HugeMed Medical Technical Development Co., Ltd.

***Legally binding signature, Function*:** _____ *(General Manager and the person responsible for regulatory)*

Place, date: Shenzhen, Guangdong *2022/03/21*

Annex 1 Product

No	Product Name	Model	Brief Introduction
1	Flexible Video Ureterorenoscope	HU30	Single use endoscope handle
		HU30S	Single use endoscope handle
2		HU32	Reusable endoscope handle
3		HUV-01	Medical Video Endoscope Image Processor

Annex 2 Applicable Standard(s)

1 EN ISO 13485:2016

2 EN ISO 14971:2019

3 EN 60601-1:2006/A1:2013

4 EN 60601-1-2:2015/A1:2021

5 EN 60601-2-18:2015

6 ISO 10993-1:2018

7 EN ISO10993-5:2009

8 EN ISO10993-10:2013

9 EN 62304:2006/ A1:2015

10 EN ISO 17664:2017

11 EN 62366-1:2015+A1:2020

12 EN 60601-1-6:2010

13 EN ISO 15223-1:2016

14 EN 1041:2008

15 EN ISO 80369-7:2021

16 EN ISO 10993-7-2008

17 EN ISO 11135:2014/A1:2019

18 EN ISO 11137-1:2015

19 ISO 8600-1:2015

20 ISO 8600-3:2019

21 ISO 8600-4:2014

22 ISTA 2A: 2011

23 IEC 60068-2-78:2012 RLV

24 ASTM F1980-16

25 ASTM D 3078-02(2013)

26 ASTM F 1929-15

27 DIN 58953-6:2016

28 ASTM F 88/F 88M-15

29 ASTM F1140/F1140M-2013