

## 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

**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



| Certificate                                                 | Initially issued | Last renewal | Valid until |
|-------------------------------------------------------------|------------------|--------------|-------------|
| Full Quality Assurance System Certificate No.:<br>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         | 16 | EN ISO 10993-7-2008       |
| 2  | EN ISO 14971:2019         | 17 | EN ISO 11135:2014/A1:2019 |
| 3  | EN 60601-1:2006/A1:2013   | 18 | EN ISO 11137-1:2015       |
| 4  | EN 60601-1-2:2015/A1:2021 | 19 | ISO 8600-1:2015           |
| 5  | EN 60601-2-18:2015        | 20 | ISO 8600-3:2019           |
| 6  | ISO 10993-1:2018          | 21 | ISO 8600-4:2014           |
| 7  | EN ISO10993-5:2009        | 22 | ISTA 2A: 2011             |
| 8  | EN ISO10993-10:2013       | 23 | IEC 60068-2-78:2012 RLV   |
| 9  | EN 62304:2006/ A1:2015    | 24 | ASTM F1980-16             |
| 10 | EN ISO 17664:2017         | 25 | ASTM D 3078-02(2013)      |
| 11 | EN 62366-1:2015+A1:2020   | 26 | ASTM F 1929-15            |
| 12 | EN 60601-1-6:2010         | 27 | DIN 58953-6:2016          |
| 13 | EN ISO 15223-1:2016       | 28 | ASTM F 88/F 88M-15        |
| 14 | EN 1041:2008              | 29 | ASTM F1140/F1140M-2013    |
| 15 | EN ISO 80369-7:2021       |    |                           |