

EC Declaration of Conformity

Manufacturer:

Shanghai Huifeng Medical Instrument Co., Ltd.
 Building No.2, No.885, Qiuxing Road, Nicheng
 Town, Pudong New Area, Shanghai, China 201306
 SRN:CN-MF-000022480

whose single Authorized

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

EU-Representative:

We, the manufacturer, herewith declare that the products:

Product Name	Shadowless Operating Lamp
Classification	Class I
EMDN	Z120107 OPERATING THEATRE LIGHTING SYSTEMS
BASIC-UDI-DI	69457986HFSOL001KS
Model	700/500LED、500/500LED、700/700LED、SY02-LED3+5、SY02-LED3+3、SY02-LED3+5D、SY02-LED3+3D、HF-L3+4CLED HF-L4+4CLED HF-L3+3CLED、YD02-LED5+5、YD02-LED4+5、YD02-LED3+5、YD02-LED3+4、YD02-LED3+3、YD02-LED4+4、HF-L25+L25CLED、ZF700/500、ZF700/700、ZF500/500、ZF600/600 YD02-5+5LED、SY02-LED5D、SY02-LED3D、SY02-LED5、SY02-LED3、SY01-LED3、SY01-LED3E SY01-LED3A、HF-L3CLED、HF-L3SLED、HF-L3SELED、HF-L3WLED、HF-L4CLED、HF-L4SLED、HF-L4SELED HF-L4WLED YD02-LED5、YD02-LED4、YD02-LED3、YD02-LED5W、YD02-LED4W、YD02-LED3W、700LED、500LED、700SLED、700WLED、700ELED、500SLED、500WLED、500ELED、YD01-LED5、YD01-LED4、YD01-LED3、YD01-LED5E、YD01-LED4E、YD01-LED3E、YD01-4LED、YD01-4ELED、YD01-5LED、YD01-5ELED、YD02-5LED、YD02-5WLED、YD01-4、YD01-4E、YD01-5、YD01-5E、HF-L25CLED、HF-L25WLED、HF-L25LED、HF-L25ELED、HF-280LED、HF-280CLED HF-280WLED、YD200LED、YD200、YD200ELED、YD200E、YD200CLED、YD200C YD200WLED、YD200W、YD300LED、ZF700、ZF600、ZF500、ZF700S、ZF700E、ZF600S ZF600E、ZF500S、ZF500E、YD01-ILED、YD01-IELED、YD01-I、YD01-IE、YD01-II、YD50LED、YD01-1SA、YD01-1SE、YD150LED、YD150NLED、YD01ALED、YD01A、YD01WLED、YD01W YD01AELED、YD01AE



meet the provisions of Directive 2017/745(EU) which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulations 2017/745(EU). It bears the mark



Following the procedure relating to the EC Declaration of conformity set in Annex IV of Regulations 2017/745(EU) and Conformity assessment procedure: ANNEX II+ III in conformity to the following standards or other normative documents

<i>ISO13485:2016</i>	<i>ISO 15223-1:2016</i>
<i>ISO 14971:2019</i>	<i>EN60601-2-41-2009+A1-2015</i>
<i>IEC60601-1-2:2014</i>	<i>IEC 60601-1: 2005 + A1:2012</i>

The above mentioned declaration of conformity is exclusively under the responsibility of

Shanghai Huifeng Medical Instrument Co., Ltd.
Building No.2, No.885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China 201306

Shanghai May 31. 2022
Place, date

Huihua Shao
Legally binding signature, Function

A red circular stamp with the text 'SHANGHAI HUIFENG MEDICAL INSTRUMENT CO., LTD.' around the perimeter and Chinese characters '上海汇丰医疗器械有限公司' in the center. The signature 'Huihua Shao' is written across the stamp.