Declaration of Conformity

according to REGULATION (EU) 2017/745

DoC Number	DoCMV01****01
Manufacturer	
Name	MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Address	12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
SRN	/
Product Information	
Product Name	Vein Illuminator
Model/Specification	NAVI-30, NAVI-60
Basic UDI-DI	69268026MV01000001VZ
CND Code	V9099
Classification	Class I, Rule 13
Conformity Assessment Procedure	Annex II, Annex III, and article 19
Notified Body	
Name	N/A
Address	N/A
Identification number	N/A
(EC) Certificate(s)	N/A
European Representative	
Name	Shanghai International Holding Corp. GmbH
Address	Eiffestrasse 80, 20537 Hamburg, Germany
Applied Regulations, Directives, Standards, and Common Specifications	See the attached list

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. herewith declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 on medical devices and the regulations, directives, standards, and common specifications in the attached list. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the DoC.

Signature	
Name, Title	Sophia Sun, Management Representative
Signature, Date	2021.05.26.

List of Applied Regulations, Directives, Standards, and Common Specifications

No.	Document No.	Name
1	EN 13485:2016/AC:2016	Medical devices - Quality management systems -Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
3	Regulation (EU) 2017/745	Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices
4	IEC 60601-1:2012	Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential performance
5	IEC60601-1-2:2014	Medical Electrical Equipment - Part1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic compatibility– Requirements and tests
6	IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes-Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
7	ISO 15223-1:2016	Medical devices.Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
8	EN 1041:2008+A1: 2013	Information supplied by the manufacturer of the medical devices
9	ISO 780:2015	Packing-Pictorial marking for handling of goods
10	ISO 2248:1985	Packaging-Complete, filled transport packages-Vertical impact test by dropping
11	IEC 62304: 2015	Medical device software-Software life cycle processes
12	IEC 62366-1: 2015	Medical devices – Part 1: Application of usability engineering to medical devices
13	IEC 60529:2013	Degrees of protection provided by enclosures(IP Code)