EU Declaration of Conformity

Manufacturer:
Qualmedi Technology Co.,Ltd.
Address:
A302 Room, 23 HangBu Road, High-tech Zone, Hefei City, Anhui Province, China.

EC-Representative:
Kingsmead Service B.V.
Address:
Zonnehof, 36 2632 BE Nootdorp

We declare under our sole responsibility that

Products: Vein Finder **Model:** QV-500，QV-600
UMDNS: 14346
Class: I (According to Annex VIII Rule 13 of Regulation (EU) 2017/745）

Intended Use： Vein finder can help medical professionals to locate certain superficial veins. This equipment is intended to be used as a supplement to appropriate medical training and experience.

BASIC UDI-DI code: QV-500(697401159QV-500DK / GS1)

QV-600(697401159QV-600DQ / GS1)

Manufacturer SRN code: CN-MF-000028309

EC Representative SRN code: NL-AR-000002066

Conformity assessment procedure: Conformity assessment procedure According to Art. 52 section 1 and 7 Regulation EU 2017/745

meet the provisions of the Regulation (EU) 2017/745 in national laws which apply to it, and of RoHS Directive 2011/65/EU Annex II amending Annex (EU)2015/863 and amending Annex (EU)2017/2102

Applied standards:

EN ISO 15223-1:2021	EN ISO 14971:2019/A11:2021	ISO 13485:2016
EN ISO 20417:2021	IEC 60601-1-2:2014+A1:2020	IEC 60601-1:2005+AMD1:2012
MEDDEV 2.7.1: REV4.	EN ISO 10993-1:2020	

The CE Mark: CE

For and on behalf of
Qualmedi Technology Co., Limited
安徽康沐醫療器械科技有限公司

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

Authorized Signature(s)

Company: Qualmedi Technology Co.,Ltd.
Address: A302 Room, 23 HangBu Road, High-tech Zone, Hefei City, Anhui Province, China.

Hefei，2023-01-01
Place，Date

General Manager, JASON ZHANG
Duly authorized to sign this Authorization on behalf of:
Qualmedi Technology Co., Ltd.