

EU Declaration of Conformity

Manufacturer information:

Name: Shenzhen Enmind Technology Co., Ltd.

registered trade name(or registered trade mark):ENMIND

Address: Room 201, Block A, No.1, Qianhai Road 1, Qianhaishen Port Cooperative District, Shenzhen, 518000 Guangdong, China

SRN: CN-MF-000015859

Authorised Representative information:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

Product covered by the EU declaration of conformity:

Product name: Vein Viewer

Model: VV-100

BASIC-UDI-DI: 697100143 006001 CU

EMDN Code: Z120499

Risk class: Class I (In accordance with the rule 13 set out in Annex VIII of REGULATION (EU) 2017/745).

CS:

ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer

ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

EN 60601-1:2006+A1:2013 Medical Electrical Equipment, Part 1: General Requirements for basic Safety and essential performance

EN 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests

EN 60601-1-6:2010+A2:2021 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

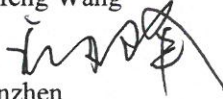
EN 62366-1:2015+A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

EN 62304:2006 Medical device software - Software life-cycle processes

We herewith declare that the device is covered by the present declaration is in conformity with REGULATION (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices and the EU declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentations are retained under the premises of the manufacturer.

Name: Junfeng Wang

Function or Title: Management representative

Signature: 

Place: Shenzhen

Date: 2022-05-31

Issue on behalf of Shenzhen Enmind Technology Co., Ltd.