

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Shenzhen Creative Industry Co., Ltd. 1001, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, 518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN (Manufacturer)	CN-MF-000009430
Name and address of Authorized Representative:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB Heerenveen, THE NETHERLANDS
SRN (EU Authorised)	NL-AR-000000551

We declare that the product concerned has been designed and manufactured under a quality management system according to Regulation(EU) MDR 2017/745 .

Medical Device:	Patient Monitor Model: AIVIEW V10 /AIVIEW V12/LeMonitor V10 /LeMonitor V12 /PH10/PH12
EMDN:	Z12030202
Risk class:	Class IIb
Basic UDI-DI:	69419006AIVIEWV12S01QX
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX Chapter I
Intended use:	Devices are used for monitoring vital physiological parameters.

The EU declaration of conformity is issued under sole responsibility of the manufacturer. We hereby declare that the above mentioned products meet the provisions of the following EUROPEAN PARLIAMENT AND OF THE COUNCIL Regulation and Applicable standards. All supporting documents are retained under the premises of the manufacturer.

Regulations	Regulation (EU) 2017/745
Applicable CS or Standard(s)	EN 60601-1: 2006+A1: 2013+A2:2021 EN 60601-1-2: 2015+A1:2021 EN 60601-1-8: 2007+A1: 2013 +A2:2021 EN 60601-2-49: 2019 EN 60601-2-27: 2014 EN 80601-2-30: 2019 EN ISO 80601-2-55: 2018 EN ISO 80601-2-61: 2019 EN ISO 80601-2-56: 2017+A1:2020 IEC 60601-2-25:2011 IEC 60601-2-34:2011 IEC 60601-2-47: 2012 IEC 62304: 2006+A1: 2015 EN 62366-1: 2015+A1:2020 EN 60601-1-6:2010+A1:2013+A2: 2020 EN ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10: 2021 ISO 10993-23:2021 EN ISO 14971:2019+A11-2021 EN ISO 15223-1:2021

Certificate No.: G15 049076 0019 Rev. 00

Issue date: 2026-02-13

CR-D-027 V1.0

Expiry date:

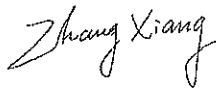
2031-02-12

Notified Body:

TÜV SÜD Product service GmbH
Ridlerstraße 65 • 80339 Munich • Germany

Shenzhen, 2026/02/13

Place, date



Zhang Xiang Management Representative

Name and function