

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:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg GERMANY
SRN (EU Authorised)	DE-AR-000000001

We declare that the product concerned has been designed and manufactured under a quality management system according to Regulation(EU) MDR 2017/745 Article 120, Annex II of 93/42/EEC and Regulation (EU) 2023/607

Medical Device:	Patient Monitor
GMDN	Model: K10/K12/K15 33586
Risk class:	Class IIb
Basic UDI-DI	69419006K15S01AK
Conformity assessment procedure:	93/42/EEC Annex II excluding(4)

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	MDR 2017/745 Article 120 93/42/EEC Regulation (EU) 2023/607
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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 60601-2-34:2014 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 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
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Certificate No.:	G1 049076 0016 REV.03; CL 049076 0017 Rev.01
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Issue date:	2025-08-29
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Expiry date:	2028-12-31
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Notified Body:

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

Shenzhen, 2025/08/29
Place, date



Zhang Xiang Management Representative
Name and function