

EC-Declaration of Conformity

(File No.CE-YM20-019 Version: A/1)

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and General Safety and Performance Requirements.

1. Object of the declaration

Product Name	Fingertip Pulse Oximeter
Model Number	YM101,YM102,YM103,YM104,YM201,YM202,YM301,YM302, YM111,YM112,YM113,YM114,YM211,YM212,YM314,YM401, YM402,YM403,YM501,YM502,YM503,YM504,YM601,YM602,YM603
Product Type	Pulse Oximeter
Intended Purpose	The Fingertip Pulse Oximeter is a reusable device and intended for spot-checking of oxygen saturation(SpO2) and pulse rate(PR) for use with the finger of adult or pediatric patients in healthcare environments. And it is not intended to be used under motion or low perfusion scenarios.
Basic UDI-DI	697291137YM4A
Global Medical Device Nomenclature Code (GMDN) and Description or EMDN Code and Description	GMDN code: 45607 Pulse Oximeter, battery-powered EMDN code: Z1203020408 Pulse Oximeter

The object of the Declaration described above is in conformity with the following regulations:

EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)
Device Risk Classification	Class IIa based on Annex VIII and Rule 10
Conformity Assessment Path	Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation
Notified Body Name, Address, and ID	NB Name: SGS FIMKO OY Address: Takomotie 8,00380,Helsinki,Finland NB Code: 0598
Certificate(s) issued	(EC) Certificate(s):FI26/1008021,Issue1 Expire date of the Certificate: 2031-04-02 Start of CE Marking:2026-04-02
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. EN ISO 14155:2020, EN ISO 14971:2019+A11:2021, EN 60601-

	1:2006+A1:2013+A2:2021, EN 60601-1-2:2015+A1:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 15223-1:2021, EN 60601-1-11:2015+A1:2021, EN 60601-1-6:2010+A1:2015+A2:2021, EN 62366-1:2015+A1:2020, EN ISO 80601-2-61:2019, EN ISO13485:2016+A11:2021, EN 62304:2006+A1:2015
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EU Directive	Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)
Device Classification	Category 8, medical device, according to Annex I
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. IEC 62474:2018, EN IEC 63000:2018, IEC 62476:2018, EN 62321-1:2016, EN 62321-2:2014, EN 62321-3-1:2014, IEC 62321-1:2021, IEC 62321-2:2021, IEC 62321-3-1:2021

2. Additional information

Manufacturer	Name: Shenzhen Yimi Life Technology Co., Ltd. Address: 302 Building C , YouLiTong Technology Industrial Plant ,No.56 Qingsong Road , Laokeng Community , Longtian Street , Pingshan District , 518118 Shenzhen ,P.R. China. SRN: CN-MF-000029928
EU Authorized Representative	Name: Share Info GmbH Address: Am Schulzentrum 12, 41564 Kaarst, Germany. SRN: DE-AR-000005132

Signature (signed for and on behalf of Shenzhen Yimi Life Technology Co.,Ltd.

Date of Issue: 2026-04-02

Shande Peng

Printed Name: Shande Peng

Place of Issue: Shenzhen City

Title: General Manager