

DECLARATION OF CONFORMITY TO COUNCIL REGULATION (EU) 2017/745 CONCERNING MEDICAL DEVICES

MANUFACTURER:	Shenzhen Creative Industry Co., Ltd. Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN OF the MANUFACTURER:	CN-MF-000009430
MEDICAL DEVICE:	SpO2 Probe Cable Extender
MODEL:	2909-0000004/2909-00000034/2909-0000035
INTENDED USE:	The Cable Extender is used to connect a compatible patient monitor or a pulse oximeter device and a SpO2 Probe. It ensures that there is enough length for the SpO2 Probe to acquire oxygen saturation(SpO2) and pulse rate(PR) from a patient.
CLASSIFICATION - ANNEX VIII:	Class I, Rule 1
BASIC UDI-DI:	69419006CableExtender3U
CONFORMITY ASSESSMENT ROUTE:	Annex II+ Annex III

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL REGULATION (EU) 2017/745 CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

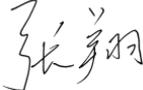
EN ISO 15223-1:2021	EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2013	

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EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

SRN OF the EUROPEAN REPRESENTATIVE: DE-AR-000000001

PLACE, DATE OF DECLARATION: Shenzhen, Mar.29, 2022

SIGNATURE: 

NAME: Zhang Xiang
POSITION: Management Representative