

EC DECLARATION OF CONFORMITY

Name and address of the firm
Shenzhen Jumper Medical Equipment Co., Ltd.
D Building, No. 71, Xintian Road, Fuyong Street,
Baoan, Shenzhen, Guangdong, China
Post Code:518103

We declare under our sole responsibility that

the medical device
Pulse oximeter
JPD-500A, JPD-500B, JPD-500C, JPD-500D, JPD-510D, JPD-500E,
JPD-510E, JPD-500F, JPD-501F, JPD-502F, JPD-500G, JPD-501G,
JPD-502G, JPD-500H, JPD-500I, JPD-510I

of class
Class IIa, Rule 10
According to the classification principle in Annex VIII of Regulation (EU) 2017/745

SRN
CN-MF-000014343

Basic UDI-DI
69517405SP01TL

meets all the provisions of the Regulation (EU) 2017/745 which apply to it.

Applied harmonised standards, national standards or other normative documents
EN ISO 15223-1:2021 / EN ISO 20417:2021 / EN ISO 14971:2019+ A11:2021
EN ISO 10993-1:2020/ EN ISO 10993-5:2009 / EN ISO 10993-10:2023
EN 60601-1:2006+A1:2013+A2:2021
EN 60601-1-2:2015+A2:2021
EN ISO 80601-2-61:2019
EN 60601-1-11:2015+A1: 2021
EN 60601-1-6:2010+A1:2015+A2:2021/ EN 62366-1:2015+A1:2020
EN 62304:2006+A1:2015
EN ISO 13485:2016+A11:2021

Conformity assessment procedure
This declaration of conformity is based on the Regulation (EU) 2017/745, Annex IX (I, III and TDA in Section 4).

Notified Body (if consulted)
SGS FIMKO OY
NB 0598

European Representative
MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

Authorized Representative's SRN
DE-AR-000000087

CE certificate No.
FI24/1008005

2023-03-06 Shenzhen, China

Manufacturer: Shenzhen Jumper Medical Equipment Co., Ltd.

Name and function

