

EU DECLARATION OF CONFORMITY

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Manufacturer: Orantech Inc.

Zone#A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming
New District, Shenzhen, China.518106

EC- Representative: Cables and Sensors B.V.

Zekeringstraat 21B
1014 BM Amsterdam, Netherlands

Product Name : SpO2 Sensor

Product Models : Please see the Annex I

UMDNS Code : 17594

Classification : Class IIb, Rule10 (According to Annex IX of directive 93/42/EEC)

Conformity Assessment Route : Annex II excluding 4 of directive 93/42/EEC

We, Orantech Inc., herewith declare under our sole responsibility that the stated medical devices meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June, 1993 concerning medical devices; including, on March 21, 2010, the amendments by council directive 2007/47/EEC. All supporting documents are retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for doc.

Standard Applied :

EN ISO 14971:2012	MEDDEV 2.7.1 Rev 4
IEC 60601-1:2005/A1:2012	IEC 60601-1-2:2014
EN ISO 15223-1:2016	EN 1041:2008
EN62366 : 2015	ISO80601-2-61:2017(E)
EN ISO 10993-1:2018	EN ISO 10993-5:2009
EN ISO 10993-10:2010	

Notified Body : TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany

CE mark: 

EC Certificate No : G1 098084 0003 Rev. 01

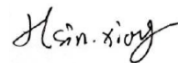
Valid Date From : 2020-01-10

Valid Date Until : 2024-05-26

Place, Date of Issue :

Shenzhen, Jan. 10, 2020

Signature :



Position: General Manager

Orantech Inc.

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Annex I List of SpO2 Sensor

Reusable SpO2 Sensor	
SS-XXX-AFXX	Adult Finger Clip SpO2 Sensor
SS-XXX-PFXX	Pediatric Finger Clip SpO2 Sensor
SS-XXX-ASXX	Adult Soft Tip SpO2 sensor
SS-XXX-PSXX	Pediatric Soft Tip SpO2 sensor
Disposable SpO2 Sensor	
SSD-XXX-XXXA	Disposable Adult SpO2 Sensor
SSD-XXX-XXXP	Disposable Pediatric SpO2 Sensor
SSD-XXX-XXXI	Disposable Infant SpO2 Sensor
SSD-XXX-XXXAN	Disposable Adult/Neonate SpO2 Sensor
SSD-XXX-XXXPI	Disposable Pediatric/Infant SpO2 Sensor