

EC Declaration of Conformity

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
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European Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestraße 80, 20537 Hamburg , GERMANY
 Tel: +49-40-2513175 Fax: +49-40-255726
 E-mail: antonsissi@hotmail.com
Product Category: Pulse Oximeter
Model (code): P300 Intelli IT(HPO-300T)
Classification for MDD: Class IIa, rule 10 to Annex IX of the MDD
Product Category for RoHS: Category 8 (Medical devices)

We herewith declare that the above mentioned product meets the provisions of the following European Committee Council Directives and Standards. All supporting documentation are retained at the premises of the manufacturer and the notified body. This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

Directives

General applicable directives:	Medical Device Directive 93/42/EEC
Standards	EN ISO13485:2016/AC:2018 EN ISO 14971:2012 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 60601-1-11:2010 ISO 80601-2-61:2011 ISO 10993-1:2018 EN ISO10993-5:2009 EN ISO10993-10:2010 EN ISO15223-1:2016 EN1041:2008 EN 62304-2006+A1:2015
Notified Body:	TÜV SÜD Product service GmbH
Address:	Ridlerstr 65, D-80339 München, Germany
ID No:	0123
Certificate Registration No:	G1 057571 0003 Rev.00
General applicable directives:	Radio Equipment Directive 2014/53/EU
Standards:	EN 300 328 V2.1.1 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 62479:2010 EN 62368-1:2014+A11:2017
General applicable directives:	RoHS Directive 2011/65/EU and its amendment (EU)2015/863
Standards	EN IEC 63000:2018 EN 62321:2009

Place / Date: Beijing/2021-02-26

Signature:

Haiying Zhao

Name: Haiying Zhao
 Position: Quality Director