Shenzhen Aeon Technology Co.,Ltd
深圳市正生技术有限公司

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	**Shenzhen Aeon Technology Co., Ltd**
Business address:	**RM6H02, Block 27-29, Tianxia IC Industrial Park, Majialong, No.133 of Yiyuan road, Nantou street, Nanshan District, 518052 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**
Medical device(s):	**A310 Fingertip Pulse Oximeter**
Classification:	**Medical Device Class IIa**
GMDN code and term:	**17148 Oximeter, pulse** **A pulse oximeter intended for the non-invasive measurement of SpO2 oxygen saturation and blood pulse rate.**
Scope of application:	All Products to which the full quality assurance procedures applies, all ranges of batches, all lots, all serial numbers, all times of manufacture.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:

EC certificate

Full Quality Assurance System
European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Devices;

No.: G1180173767012

ISO 13485: 2016

No.: Q5180173767011

Design examination certificate (if applicable): **No applicable**

Standards applied: *LIST OF STANDARDS*

1.	MDD 93/42/EEC
2.	ISO13485:2016
3.	IEC 60601-1:2005 +CORR.1:2006+ CORR.2:2007+A1:2012
4.	EN IEC 60601-1-2: 2014
5.	IEC 60601-1-11:2015
6.	ISO 80601-2-61:2011
7.	ISO 9919: 2009
8.	EN ISO14971:2012
9.	ISO10993-5:2009
10.	ISO10993-10:2010
11.	EN 62304:2015
12.	EN 62366:2015
13.	ISO 15223-1:2016
14.	EN1401:2008
15.	MEDDEV 2.7.1: 2016 REV.4

Authorised signatory:

Signature : _____

SHENZHEN AEON TECHNOLOGY CO.,LTD.
深圳市正生技术有限公司
SHENZHEN CHINA
中国 深圳

Name: Raymond Xie Position: General Manager