Declaration of Conformity

For the following products:

Fingertip Pulse Oximeter

(Product Name)

AS-301, AS-302, AS-303, AS-301-L, AS-302-L, AS-304, AS-304-L

Please Note:model AS-304-L corresponds to customer's model Dr.Frei AS-304-L

CONFORMITY ASSESSMENT ROUTE: Annex II excluding section 4

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC

EN ISO14971: 2012, ENISO 15223-1:2016, EN 1041: 2008,
EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, ISO80601-2-61:2011
ENISO13485:2016, EN60601-1-6:2010 EN 62304:2006, EN ISO 10993-1:2009, EN ISO 10993-10:2010,
EN ISO 10993-5:2009, EN62366:2008 EN60601-1-11:2011

The following representative in Europe is responsible for making this declaration:

Company Name: MedNet GmbH

Company Address: Borkstrasse 10,48163. Münster, Germany

Tel: +49 251 32266-0, Fax +49 251 32266-22

The following manufacturer is responsible for making this declaration:

Manufacturer Name: SHENZHEN ACURIO INSTRUMENTS CO., LTD

Add: 502G Part B, Donglian Building, Chuangye 2nd Road, 23rd Subdistict, Baoan District, Shenzhen, China

Country: China

Tel: +086-(0755) 26701114 26701115

Fax: +086-(0755) 21677669

Website: www.acurio.cn

Notified Body:

Company Name: DNV GL PRESAFE AS

Company Address: Veritasveien 3, N-1363 Høvik Postbox 116, N-1300 Sandvika

Website: www.dnvgl.com

Notified Body number: CE 2460

Digitally signed by Cimpoieş Inga
Date: 2021.05.24 16:38:56 EEST
Reason: MoldSign Signature
Location: Moldova

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General Manager

(Legal Signature) (Position/title)

2020.3.29

(Date)