

# 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 2<sup>nd</sup> Road, 23<sup>rd</sup> Subdistrict, Baoan District, Shenzhen, China

Country: China

Tel: +086-(0755) 26701114 26701115

Fax: +086-(0755) 21677669


Website: [www.acurio.cn](http://www.acurio.cn)

## Notified Body:

Company Name: DNV GL PRESAFE AS

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

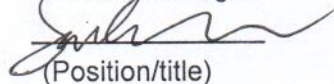
Website: [www.dnvgl.com](http://www.dnvgl.com)

Notified Body number:  2460

刘平

(Legal Signature)

General Manager

  
(Position/title)

