

DECLARATION OF CONFORMITY

We

Name and address of manufacturer:

Shenzhen Brav Electronic Technologies Co.,Ltd

4/F, Block11, Tongfuyu Industry District, Lezhujiao, Jiuwei, Xixiang, Baoan, Shenzhen, P.R.China

declare on our own responsibility that

the medical device

Infrared Thermometer

IT-901, IT-121, IT-121S, T-905, IT-906, IT-907, IT-122, IT-123, IT-124, IT-125,

IT-126, IT-127, IT-128, IT-129

Digital Clinical Thermometer

DT-121, DT-122

meets all applicable requirements of the Directive 93/42/EEC Annex I, as amended by Directive 2007/47/EC.
The manufacturer is exclusively responsible for the declaration of conformity.

Applied standards :

*EN ISO 14971:2012, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN ISO10993-5:2009,
EN ISO10993-10:2010, EN ISO 15223-1:2016, EN 60601-1-11:2010, EN60601-1-6:2010,
EN 62366:2008, EN ISO 80601-2-56:2012, EN 60601-1-8:2007, EN 62304:2006, EN ISO13485:2016*

Classification:

*Classified as class **Ila** according to Annex IX,*

*Rule **4. 9.10** of the Directive 93/42/EEC.*

Conformity assessment procedure:

*Conformity assessment was performed according to
Annex V of the Directive 93/42/EEC.*

The Authorized Representative within the
EU who has been empowered to enter into
commitments on our behalf is:

MedNet GmbH

Borkstrasse 10

48163 Münster, Germany

Notified Body:



DNV GL Nemko Presafe AS

Veritasveien 3, N-1363 Høvik Postbox 116,

N-1300 Sandvika

2018.11.05-2023.09.29

Validity period

Shenzhen, 2018.12.24

place, date

.....
legally binding signature

Kay Wang (General Manager)

name and function