EC Declaration of Conformity

Manufacturer:	*whose single Authorized* **EU**-*Representative:*
Shenzhen BSX Technology Electronics Co., Ltd. Rm101&2/F~4/F, Building No.13, Ailian Industrial park, Wulian Community, Longgang District, Shenzhen 518116 Guangdong P.R. China	MedNet EC-REP GmbH Borkstrasse 10, 48163 Münster, Germany

We, the manufacturer, herewith declare that the products

Product： Arm Type Electronic Blood Pressure Monitor

Model Code: BSX523, BSX538, BSX501, BSX515, BSX516, BSX525, BSX583, BSX561, BSX593, BSX595

Standard:
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012;
ANSI/AAMI ES 60601-1:2005+A2 (R2012) +A1; EN 60601-1:2006+A11:2011+ A1:2013+ A12:2014; IEC 60601-1-11:2015; EN 60601-1-11:2015; IEC 80601-2-30:2009/AMD1:2013;
EN 80601-2-30:2010/A1:2015, EN 60601-1-2:2015, IEC 60601-1-2:2014,
EN 60601-1-11:2015 clause12 IEC 60601-1-11:2015 clause12,
EN 80601-2-30:2010+A1 clause202
IEC 80601-2-30:2009+A1 clause202

All supporting documentation is retained at the premises of the Manufacturer.

Product： Wrist Digital Blood Pressure Monitor

Model Code： BSX322, BSX325

Standard:
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012),
EN 60601-1:2006+ A11:2011+A1:2013+A12:2014, IEC 60601-1-11:2015,
EN 60601-1-11:2015, IEC 80601-2-30:2009+A1:2013, EN 80601-2-30:2010+A1:2015.
EN 60601-1-2:2015, IEC 60601-1-2:2014, EN 60601-1-11:2015 clause 12,
EN 80601-2-30: 2010+A1 clause 202, IEC 80601-2-30:2009+A1 clause 202

All supporting documentation is retained at the premises of the Manufacturer.

The products comply with the essential requirements in accordance with Annex I of the Medical Devices Directive 93/42/EEC.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

Compliance of the designated product with the Directive 93/42/EEC aspects of manufacture concerned with securing and maintaining sterile conditions has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 2159545-1
Issue date: 2020-12-22
Expiry date: 2023-12-09

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shenzhen BSX Technology Electronics Co., Ltd.

Rm101&2/F~4/F, Building No.13, Ailian Industrial park, Wulian Community, Longgang District, Shenzhen 518116 Guangdong P.R. China

Shenzhen 01-12-2021
Place, date

Fangkeu
Legally binding signature, Function