

EC Declaration of Conformity

Certificate No.: ML161116001

Manufacturer:
Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei, 11492, Taiwan, R.O.C.

whose single Authorized Representative:
Microlife AG
9443 Widnau / Switzerland

We, the manufacturer, herewith declare that the products

Products:	UMDNS	GMDN
Blood pressure measurement, electronic, ProBP 2400	16-157	16173

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX rule 10 of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

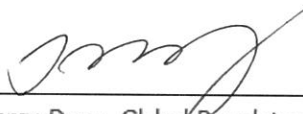
Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV NORD CERT GmbH
Langemarckstr. 20, D-45141 Essen
Certificate No.: 04 232 950010
Validity from: 2016-10-22
until: 2019-10-21

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC, and in conformity to the following standards or other normative documents:

EN 60601-1:2006/AC: 2010 (IEC 60601-1: 2005+CORR.1 (2006)+CORR.2(2007))
EN 60601-1-2: 2007/AC: 2010 (IEC 60601-1-2: 2007)
EN 62304: 2006/AC: 2008 (IEC 62304: 2006)
EN 60601-1-6: 2010 (IEC 60601-1-6: 2010)
EN ISO 10993-1: 2009/AC: 2010 (ISO 10993-1:2009/Cor 1:2010)
EN ISO 10993-5: 2009(ISO 10993-5: 2009)
EN ISO 10993-10: 2010(ISO 10993-10: 2010)
EN ISO 10993-12: 2012 (ISO 10993-12: 2012)
EN ISO 14971: 2012(ISO 14971: 2007)
EN 980: 2008
EN1041: 2008
EN 80601-2-30: 2010(IEC 80601-2-30: 2009)
ANSI/AAMI/ISO 81060-2: 2013

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


Jimmy Deng, Global Regulatory Manager

2016-11-16
Issued Date