EC Declaration of Conformity

Certificate No.: ML150209001

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

CE 0044

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: 2013-10-06
until: 2016-10-21

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/A1:2013 (IEC 60601-1:2005/A1:2012)
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)
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
EN 1041:2008
ANSI/AAMI/IEC/ISO 80601-2-30:2009+A1:2013
ANSI/AAMI/IEC/ISO 81060-2:2013

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

Jimmy Deng/Manager, Global Regulatory

2015.02.09
Issued Date