

# EC Declaration of Conformity

Certificate No.: ML191114001

*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/product category  
**Automatic-inflation electronic** GMDN 45617  
**sphygmomanometer, portable, arm/wrist**  
**Manual-inflation electronic sphygmomanometer,** GMDN 47489  
**portable**  
**(Blood pressure measurement, electronic)** (UMDNS 16-157)  
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

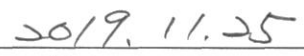
**TÜV NORD CERT GmbH**  
**Langemarckstr. 20, D-45141 Essen**  
Certificate No.: 04 232 950010  
Validity from: 2019-10-22  
Expiry date: 2024-05-26

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:

EN1060-1:1995+A2:2009  
EN1060-3:1997+A2:2009  
EN1060-4:2004  
EN 60601-1:2006+A1:2013+AC: 2014 (IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012(or IEC60601-1:2012))  
EN 60601-1-2:2015 (IEC 60601-1-2:2014)  
EN 60601-1-11:2010(IEC 60601-1-11:2010)  
EN 62304:2006/ A1:2015 (IEC 62304:2006+AMD1:2015)  
EN 60601-1-6:2010/A1:2015 (IEC 60601-1-6:2010+A1:2013)  
EN 62366-1:2015(IEC 62366-1:2015)  
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 10993-10:2013(ISO 10993-10:2010)  
EN ISO 10993-12:2012 (ISO 10993-12:2012)  
EN ISO 14971:2012(ISO 14971:2007)  
EN ISO 15223-1:2016(ISO 15223-1:2016)  
EN1041:2008

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

  
Ariel Wang, Global RA & QM director

  
Issued Date