MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

DECLARATION OF CONFORMITY PROCEDURES

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Microlife Corporation
Business address:	9F, No. 431, RuiGuang Road, Nei-Hu, Taipei 11492, Taiwan, R.O.C.
Medical device(s):	Product Name: Welch Allyn ProBP 2400 Blood Pressure Cuff REF: 901097 Blood Pressure Cuff, Reusable, Pur
Classification:	Class 1
GMDN code and term:	34978 Cuff, Blood pressure, Reusable
Scope of application:	Reusable Non-Invasive Blood Pressure Cuffs, Model number: REUSE-09-2400 REUSE-11-2400 REUSE-12-2400 REUSE-12L-2400

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

For Class IIa, Class I sterile, & Class I Measurement medical devices; and for Class 1 and Class 2 IVD's choose ONE conformity assessment procedure applied to the device and include the certificate number on this declaration

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

0044 CE

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: 2019-03-31

Standards applied: EN/IEC 80601-2-30: Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

EN 1060-1: Non-invasive Sphygmomanometers - Part 1: General Requirements

EN 1060-3: Non-invasive sphygmomanometers. Supplementary requirements for electro-mechanical blood pressure measuring systems

ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing

Signature

Jimmy Deng, Manager, Global Regulatory

Name, Position

2017.03.14

Date