EU Declaration of Conformity

Certificate No.: ML20220303001

Manufacturer:
Microlife AG
Espenstrasse 139, 9443 Widnau, Switzerland

Single Registration Number(SRN): CH-MF-000013903

Whose single Authorized Representative:
Microlife UAB
P. Lukšio g. 32
08222 Vilnius, Lithuania
Single Registration Number(SRN): LT-AR-000011673

We, the manufacturer, herewith declare that the products
Cuff for Oscillometric non-invasive blood pressure monitors, reusable
Class: I
Trade Name: Microlife
Basic-UDI-DI: 4719003BPCBZ
Intended Use:
This device, a reusable cuff, is an accessory of oscillometric non-invasive blood pressure monitors, when used together, is intended to measure blood pressure of an individual. Select appropriate cuff for use with the intended arm circumference sizes.

Commercial Product Name	Cuff Model Family Number	Cuff Catalog Number
WatchBP Home S cuff	WBPC	cuff-S-WBPH
WatchBP Home M cuff	WBPC	cuff-M-WBPH
WatchBP Home L cuff	WBPC	cuff-L-WBPH
WatchBP Home L-XL cuff	WBPC	cuff-LXL-WBPH
WatchBP O3 M cuff	WBPC	cuff-M-WBPA
WatchBP O3 L cuff	WBPC	cuff-L-WBPA
WatchBP O3 L-XL cuff	WBPC	cuff-LXL-WBPA
WatchBP Office S cuff	WBPC	cuff-S-WBPO
WatchBP Office M cuff	WBPC	cuff-M-WBPO
WatchBP Office L cuff	WBPC	cuff-L-WBPO
WatchBP Office L-XL cuff	WBPC	cuff-LXL-WBPO
WatchBP Office M size cuff Ankle	WBPC	cuff-M-WBPO-Ankle
WatchBP Office L size cuff Ankle	WBPC	cuff-L-WBPO-Ankle
WatchBP wide range soft M-L cuff	WBPC	cuff-ML-WBPH
WatchBP wide range rigid M-L cuff	WBPC	cuff-ML-WBP-R

meet the provisions of Medical Device Regulation (EU) 2017/745 which apply to them.

The medical device accessory has been assigned to class I according to Annex VIII Rule 1 section 4.1 in Chapter III of the Medical Device Regulation (EU) 2017/745.
It bears the mark

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following the procedure relating to the EU Declaration of Conformity set out in Article 19 and Annex IV of Medical Device Regulation (EU) 2017/745, and in conformity to the following standards or other normative documents:

EN 80601-2-30:2010+A1:2015(IEC 80601-2-30:2009+A1:2013)
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 (ISO10993-1:2009+COR.1:2010)
EN ISO 10993-5:2009 (ISO 10993-5:2009)
EN ISO 10993-10:2013 (ISO10993-10:2010)
EN ISO 10993-12:2012 (ISO10993-12:2012)
EN ISO 14971: 2012 (ISO 14971:2007)
EN ISO 15223-1:2016 (ISO15223-1:2016)
EN ISO 13485:2016

ISO 81060-2:2018
ISO 20417:2021
MEDDEV 2.7/1 revision 4
EC/1907/2006 amended by M65 (2021/1297) and corrected by C8
2011/65/EU amended by M61 (2022/366) and corrected by C2

The above mentioned declaration of conformity is exclusively under the responsibility of Microlife AG, a subsidiary of Microlife Corporation, The validity of this Declaration expires in case of a revised declaration of conformity.

Lance 2022.3.4

Lance Huang, Product Manager, Issued Date
Microlife Corporation

DocuSigned by:
Gerhard Frick 3/4/2022
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Gerhard Frick, Regulatory Manager, Issued Date
Microlife AG