

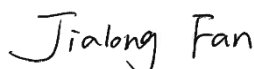
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Declaration of Conformity

TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Legal Manufacturer:	Name: Guangdong Transtek Medical Electronics Co., Ltd. Address: Zone A, No. 105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China SRN: CN-MF-000010684			
European Representative:	Name: MDSS GmbH Address: Schiffgraben 41, 30175 Hannover, Germany SRN: DE-AR-000005430			
Device Identification:	Product description	Product/trade name	Model	Catalog number
	Digital Automatic Blood Pressure Monitor	Withings BPM Pro 2	WPM07	WPM07-07
		Withings BPM Vision		WPM07-08
EMDN Code:	Z1203020501 NON-INVASIVE OSCILLOMETRIC BLOOD PRESSURE GAUGES			
Basic UDI-DI:	69328253MDR14PZ			
Device Photograph:				
Intended Purpose:	The BPM Pro 2 is a digital monitor intended for use in measuring blood pressure and pulse rate. The device is intended to be used in a human adult population (18 years old minimum) with an arm circumference of 8¾ to 16½ inches (22 to 42			

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	cm) or 15¾ to 20½ inches (40 to 52 cm). It is intended for indoor use only. The BPM Vision is a digital monitor intended for use in measuring blood pressure and pulse rate. The device is intended to be used in a human adult population (18 years old minimum) with an arm circumference of 8¾ to 16½ inches (22 to 42 cm) or 15¾ to 20½ inches (40 to 52 cm). It is intended for indoor use only.		
Risk Class:	Class IIa		
Classification Rule:	The third indent of 1 st paragraph of Rule 10		
Conformity Assessment Route:	Chapters I and III of Annex IX of the Regulation (EU) 2017/745, and technical documentation as specified in Section 4 of that Annex.		
We, Guangdong Transtek Medical Electronics Co., Ltd., hereby declare that the above-mentioned product(s) meet the following Union acts (MDR) Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for this Declaration of Conformity.			
Any CS applied:	No CS applied		
Notified Body:	Name: TÜV SÜD Product Service GmbH Address: Ridlerstrasse 65, 80339 Munchen, Germany Actor ID: 0123		
(EC) Certificate(s):	G15 082800 0052 Rev. 00	Valid until:	2031-09-02
Start of CE-marking:	2025-09-26		
Place, Date of Issue:	Zhongshan, Guangdong 2026-9-17		
Signature:	 Name: Jialong Fan Function: PRRC		

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We, Transtek, declare under our sole responsibility that the above-named products conform to the essential requirements of the following Directives:

Applied European Directives

- Medical Device Regulation (MDR): 2017/745
- Waste Electrical and Electronic Equipment (WEEE): 2012/19/EU
- RoHS: 2011/65/EU amended by (EU)2015/863

Medical Device Regulation: We declare under our sole responsibility that the devices subject to this declaration are in conformity with the standards mentioned below:

- ISO 13485:2016 (EN ISO 13485:2016+A11:2021)
- ISO 14971:2019 (EN ISO 14971:2019+A11:2021)
- ISO/TR 24971:2020
- IEC 60601-1:2005+A1:2012+A2:2020 (EN 60601-1:2006+A1:2013+A2:2021)
- IEC 60601-1-11:2015+A1:2020 (EN 60601-1-11:2015+A1:2021)
- IEC 60601-1-2:2014+A1:2020 (EN 60601-1-2:2015+A1:2021)
- IEC 60601-1-6:2010+A1:2013+A2:2020 (EN 60601-1-6:2010+A1:2015+A2:2021)
- IEC 62366-1:2015+A1:2020 (EN 62366-1:2015+A1:2020)
- IEC 80601-2-30:2018 (EN IEC 80601-2-30:2019)
- ISO 81060-2:2018+A1:2020+A2:2024 (EN ISO 81060-2:2019+A1:2020+A2:2024)
- IEC 62304:2006+A1:2015 (EN 62304:2006+A1:2015)
- ISO 15223-1:2021+A1:2025 (EN ISO 15223-1:2021+A1: 2025)
- ISO 20417:2026 (EN ISO 20417:2026)
- ISO 10993-1:2025 (EN ISO 10993-1:2025)
- ISO 10993-5:2009 (EN ISO 10993-5:2009+A11:2025)
- ISO 10993-10:2021 (EN ISO 10993-10:2023)
- ISO 10993-23:2021 (EN ISO 10993-23:2021)
- MEDDEV.2.7.1 Rev4
- MDCG 2020-13
- MDCG 2019-9 Rev.1
- MDCG 2020-5

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- MDCG 2020-6
- MDCG 2020-7
- MDCG 2022-21

Waste Electrical and Electronic Equipment Directive: The device subject to the directive 2012/19/EU is marked with the logo and Transtek supplies recycling information.

Radio Equipment Directive: The conformity assessment procedure as detailed in 2014/53/EU has been followed and performed.

Health & Safety (Article3.1(a))	- IEC 60601-1:2005+AMD1:2012+AMD2:2020 - IEC 60601-1-11:2015+AMD1:2020 - EN 62311:2020 - EN 50566:2017+A1:2023 - EN 62209-2:2010+A1:2019
EMC (Article3.1(b))	- EN 301 489-1 V2.2.3 - EN 301 489-17 V3.3.1 - EN 301 489-52 V1.2.1
Radio (Article3.2)	- EN 300 328 V2.2 .2 - EN 301 908-1 V15.2.1

RoHS Directive: The device complies with the below-mentioned standards and meets the requirements of the 2011/65/EU Directive amended by (EU)2015/863. List of RoHS restricted substances acceptance limits values tolerated and verification methods to ensure compliance:

Substances and Acceptance Limits	Verification Methods
- Mercury (0.1%)	- IEC 62321-1:2013
- Cadmium (0.01%)	- IEC 62321-2:2021
- Lead (0.1%)	- IEC 62321-3-1:2013
- PBBs (0.1%)	- IEC 62321-4:2013+A1:2017

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- PBDEs (0.1%)	- IEC 62321-5:2013
- Hexavalent Chromium (0.1%)	- IEC 62321-7-1:2015
- Phthalates (DEHP, BBP, DBP, DIBP) (0.1%)	- IEC 62321-7-2:2017
	- IEC 62321-12:2023
	- IEC 62321-8:2017
	- IEC 62321-6:2015

All other homogeneous materials comply with the applicable maximum concentration limits (0.1% for Pb/Hg/Cr(VI)/PBB/PBDE/DEHP/BBP/DBP/DIBP, 0.01% for Cd).

Signature: 

Name: Jialong Fan

Position: PRRC

Place: Zhongshan, Guangdong

Date of Issue: 2026-09-17