

**CE Technical Document****Declaration of Conformity**

Document No.: LS-DOC-MDR14-017

Version No.: A/1

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

Prepared by:

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Approved by:


Jialong Fan

PRRC

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Revision History


Version	Description of changes	Revised by	Checked by	Date
A/0	Initial release	Aimee Li	Nicole Hu	2025-09-16
A/1	Updated the date of Start of CE-marking	Aimee Li	Nicole Hu	2025-10-09

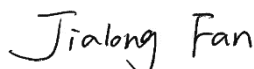
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Declaration of Conformity

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):	No. G10 082800 0048 Rev.01	Valid until:	2026-09-02
Start of CE-marking:	2025-09-26		
Place, Date of Issue:	Zhongshan, Guangdong 2025-10-09		
Signature:	<div></div> <div>Name: Jialong Fan</div> <div>Function: PRRC</div>		