

### **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	Withings BPM Pro 2	W.D. 607	WPM07-07
Pressure Monitor	Withings BPM Vision	WPM07	WPM07-08

Prepared by:	Verified by:	Approved by:
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Aimee Li	10100	
RA Engineer	RA Senior Engineer	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

Name: Guangdong Transtek Medical Electronics Co., Ltd.     Address: Zone A, No. 105, Dongli Road, Torch Development District, 5     Zhongshan, Guangdong, China     SRN: CN-MF-000010684     Name: MDSS GmbH     Address: Schiffgraben 41, 30175 Hannover, Germany     SRN: DE-AR-000005430     Product description   Product/trade name   Model   Catalog num     Digital Automatic   Withings BPM Pro 2   WPM07-   Blood Pressure   Withings BPM Vision   WPM07-   Monitor   Monitor   Withings BPM Vision   WPM07-   WPM07-	20427			
Legal Manufacturer: Zhongshan, Guangdong, China   SRN: CN-MF-000010684     European Representative:   Name: MDSS GmbH   Address: Schiffgraben 41, 30175 Hannover, Germany   SRN: DE-AR-000005430     Product description   Product/trade name   Model   Catalog number   Catalog number   WPM07-1     Device Identification:   Blood Pressure   Withings BPM Vision   WPM07-1   WPM07-	/X44/			
SRN: CN-MF-000010684  Representative:  Name: MDSS GmbH  Address: Schiffgraben 41, 30175 Hannover, Germany  SRN: DE-AR-000005430  Product description Product/trade name Model Catalog num  Digital Automatic Withings BPM Pro 2  Blood Pressure Withings BPM Vision WPM07-Monitor WPM07-				
Representative:  Name: MDSS GmbH  Address: Schiffgraben 41, 30175 Hannover, Germany  SRN: DE-AR-000005430  Product description Product/trade name Model Catalog num  Digital Automatic Withings BPM Pro 2  Blood Pressure Withings BPM Vision WPM07-  Monitor WPM07-				
Representative:  Address: Schiffgraben 41, 30175 Hannover, Germany SRN: DE-AR-000005430  Product description Product/trade name Model Catalog num Digital Automatic Withings BPM Pro 2 Blood Pressure Withings BPM Vision Monitor Withings BPM Vision WPM07-	SRN: CN-MF-000010684			
Representative:  Address: Schiffgraben 41, 30175 Hannover, Germany  SRN: DE-AR-000005430  Product description   Product/trade name   Model   Catalog num  Digital Automatic   Withings BPM Pro 2   WPM07-  Blood Pressure   Withings BPM Vision   WPM07-  Monitor   WPM07-	Name: MDSS GmbH			
SRN: DE-AR-000005430  Product description Product/trade name Model Catalog num  Digital Automatic Withings BPM Pro 2  Blood Pressure Withings BPM Vision Monitor WPM07-				
Device Identification:    Digital Automatic   Withings BPM Pro 2   WPM07-Withings BPM Vision   WPM07-W				
Device Identification:  Blood Pressure  Monitor  WPM07  WPM07-	nber			
Blood Pressure Withings BPM Vision Monitor WPM07 WPM07-	)7			
Monitor				
71202020701 NON DIVIGINE COCKETOR DECOR DECOR	)8			
Z1203020501 NON–INVASIVE OSCILLOMETRIC BLOOD PRES	SURE			
EMDN Code: GAUGES				
Basic UDI-DI: 69328253MDR14PZ				
Device Photograph:	1: 			
	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 ald minimum) with an arm singuraferance of 83/ to 161/ inches (22 to 42).			

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	withings BPM P10 2, Withings BPM Vision		
	am) on 153/ to 201/ inches (40 to 52 am)	It is intended for	u in doon was only
	cm) or 15 <sup>3</sup> / <sub>4</sub> to 20 <sup>1</sup> / <sub>2</sub> inches (40 to 52 cm). It is intended for indoor use only.		
	The BPM Vision is a digital monitor inte		-
	and pulse rate. The device is intended to	be used in a hun	nan adult population (18
	years old minimum) with an arm circur	nference of 83/4 t	to 16½ inches (22 to 42
	cm) or $15\frac{3}{4}$ to $20\frac{1}{2}$ inches (40 to 52 cm). It is intended for indoor use only.		
Risk Class:	Class IIa		
Classification Rule:	The third indent of 1st paragraph of Rule 10		
Conformity	Chapters I and III of Annex IX of the Regulation (EU) 2017/745, and technical		
Assessment Route:	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		
	Name: TÜV SÜD Product Service GmbH		
Notified Body:	Address: Ridlerstrasse 65, 80339 Munch	nen, 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		
	Jialong Fan		
Signature:	Name: Jialong Fan		
	Function: PRRC		