

	EU Declaration of Conformity (MDD)		SCHILLER The Art of Diagnostics
	CH-DHF-0958 Rev. 04	Effective Date : 21.07.2021	

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

Manufacturing Site(s): SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

EU Authorised Representative: SCHILLER Medizintechnik GmbH
Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany

EC-certificate: G1 041505 0120

Notified Body: TÜV SÜD Product Service GmbH, ID 0123

Device Relevant Information			
Trade Name	BR-102 plus PWA		
Product Type	Blood Pressure Recorder		
Intended Purpose	<p>The device is a non-invasive ambulatory blood pressure recorder. It uses auscultatory and oscillometric signals, or purely oscillometric signals to measure the blood pressure of humans. Systolic, diastolic, mean arterial pressure and heart rate are measured. It is intended as an aid to diagnosis and treatment when it is necessary to measure an adult or adolescent patients blood pressure over an extended period of time (up to 48 hours). Further with each measurement, the PWA data will be saved for subsequent external assessments.</p> <p>The BR-102 plus can be used for adults and children (>3 years) of both sexes and all ethnic origins.</p>		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	36888		
REF Number	REF #	GTIN	Description
	3.900480 (part of 0.294000)	07613365000160	BR-102 plus PWA
Standards Applied	EN 60601-1:2006 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) IEC 60601-1-11: 2011 IEC 80601-2-30: 2010 EN ISO 81060-1: 2012 EN 60601-1-6:2010 (IEC 60601-1-6: 2010) EN 62366:2008 (IEC 62366: 2007) EN ISO 10993-1: 2010 EN ISO 10993-5: 2009 EN ISO 10993-10: 2010 EN ISO 14971: 2012 EN ISO 13485: 2016		

We, the undersigned, declare that the medical device described above is in conformity with the essential requirements of 93/42/EEC (MDD) Annex 2 excluding Cl. 4. Please refer to Appendix 01 for accessories.

The device listed above is in conformity with applicable provisions of the Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.



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The device that is covered by the present declaration is in conformity with *DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.*

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. The products are CE marked with notified body number.



This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 21 July 2021

Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY
MANAGEMENT

Signature

Name: VALENTINA SHCHERBA

Title / Function: HEAD OF REGULATORY
AFFAIRS

Signature



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Appendix 01 Accessories/devices compatible to the device(s) covered by this declaration:

SCHILLER AG REF No.	Accessory/Device name	REF No. as per Label	Legal Manufacturer
2.156077	Premium reusable pouch red BR-102 plus / BR-102 plus PWA.	13487A	SHELL CASE
2.156079	Premium accessories case red including reusable pouch red.	13483A	SHELL CASE
2.156086	Holter pouch single use, white, set of 50	JT1210101	JT TECH
2.156088	Shoulder and waist strap for premium reusable pouch red BR-102 plus / BR-102 plus PWA.	15651A	SHELL CASE
2.200179	Charging unit BR-102 plus / BR-102 plus PWA, BP-200 plus, MS-12blue, 90-264 VAC (4 batteries can be charged at the same time).	MODEL PC02	HY-LINE
2.310215	USB / mini USB cable for MT-101, BR-102 plus / BR-102 plus PWA, BP-200plus, TM-1.	AR001-LB350B00R	HSUAN MAO
2.100326	Adhesive plaster for microphone, BR-102, BR-102 plus / BR-102 plus PWA and BP-200 plus, set of 10.	See SCHILLER AG REF No.	SCHILLER AG
2.120053	Blood pressure cuff 2008 with bladder, size XS, 7.5-13 cm, BR-102 plus / BR-102 plus PWA for oscillometric measurement only.	34-85-390	ERGOSANA
2.120057	BP buckle cuff 2014 with bladder, size S, 18-26cm, for BR-102 plus / BR-102 plus PWA, BP-200 plus.	34-84-371	ERGOSANA
2.120058	BP buckle cuff 2014 with bladder, size M, 25-35cm for BR-102 plus / BR-102 plus PWA, BP-200 plus.	34-84-311	ERGOSANA
2.120059	BP buckle cuff 2014 with bladder, size L, 35-45cm, for BR-102 plus / BR-102 plus PWA, BP-200 plus.	34-84-331	ERGOSANA
2.120062	BP buckle cuff 2014 & buckle, Size M, complete with microphone and tube BR-102 plus / BR-102 plus PWA for auscultatory measurement.	84-11-310	ERGOSANA
2.120061	BP buckle cuff 2014, Size M, with tube for oscillometric measurement Only	85-11-310	ERGOSANA
2.120054	Tube for BP cuffs 2008 and 2014 BR-102 plus for oscillometric measurement only	21-85-301	ERGOSANA
2.120063	BP velcro cuff 2014, size XS, BR-102 plus for oscillometric measurement only	See SCHILLER AG REF No.	SCHILLER AG
2.120064	BP velcro cuff 2014, size S, BR-102 plus, BP-200 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120065	BP velcro cuff 2014, size M, BR-102 plus, BP-200 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120066	BP velcro cuff 2014, size L, BR-102 plus, BP-200 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120067	BP velcro cuff 2014, size XL, BR-102 plus, BP-200 plus	See SCHILLER AG REF No.	SCHILLER AG



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2.120068	Comfort fleece size XS, package of 10, for BP cuff 2.120063	See SCHILLER AG REF No.	SCHILLER AG
2.120069	Comfort fleece size S, package of 10, for BP cuff 2.120064	See SCHILLER AG REF No.	SCHILLER AG
2.120070	Comfort fleece size M, package of 10, for BP cuff 2.120065	See SCHILLER AG REF No.	SCHILLER AG
2.120071	Comfort fleece size L, package of 10, for BP cuff 2.120066	See SCHILLER AG REF No.	SCHILLER AG
2.120072	Comfort fleece size XL, package of 10, for BP cuff 2.120067	See SCHILLER AG REF No.	SCHILLER AG
2.120076	Cuff with buckle size 'S'	See SCHILLER AG REF No.	SCHILLER AG
2.120077	Cuff with buckle size 'M'	See SCHILLER AG REF No.	SCHILLER AG
2.120078	Cuff with buckle size 'L'	See SCHILLER AG REF No.	SCHILLER AG
2.120080	BP cuff D-ring, size S, BR-102 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120081	BP cuff D-ring, size M, BR-102 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120082	BP cuff D-ring, size L, BR-102 plus	See SCHILLER AG REF No.	SCHILLER AG
2.120050	Microphone and tube for BP cuffs 2008 and 2014 BR-102 plus for auscultatory and oscillometric measurement	21-84-301	ERGOSANA



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Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First introduce to CE-mark region (07.11.2014)	01	15.02.2019
Update to MC TMPL	02	See MC Release Date
Change legal manufacturer from Hofstetter, AR Textil to SCHILLER AG Adaption standards year indications, addition of 2015/863 (RoHS 2 amendment)	03	See MC Release date
Update to TMPL-0085 Rev.06 Added harmonized standards	04	2021-07-21