

### EU MDD Declaration of Conformity

**Manufacturer:** SCHILLER AG  
 Altgasse 68, 6341 Baar, Switzerland

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

**EC-certificate:** G1 041505 0120

**Notified Body:** TÜV SÜD Product Service GmbH, ID 0123

Device Relevant Information	
<b>Trade Name</b>	BP-200 plus
<b>Product Type</b>	Stress test blood pressure monitor
<b>Intended Purpose</b>	The BP-200 plus is intended to be used as an adjunct to exercise stress testing devices. It is intended to measure and display diastolic and systolic blood pressure, heart rate, percentage of oxygen saturation in arterial blood (SpO2) and pulse rate in adult or adolescent patients during stress tests. The BP-200 plus can be used for patients of both sexes and all races.
<b>Risk Class acc. to Annex II MDD</b>	Ila
<b>GMDN Code</b>	16173
<b>REF Number(s) and description</b>	3.930300 base device 3.930301 base device SPO2 3.930305 base device ECG (part of 0.310000 complete)
<b>Standards Applied</b>	IEC 60601-1: 2012 IEC 60601-1-2: 2014 IEC 60601-1: 2012 IEC 80601-2-30: 2009 ISO 80601-2-61:2011 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 that is covered by the present declaration is in conformity with Dir. 2011/65/EU (Art. 4) of the European Parliament and of the Council of 8 June 2011 on the restriction of use of certain hazardous substances (RoHS).

This declaration of conformity is issued under the sole responsibility of SCHILLER AG.


This declaration is valid until 16 April 2024 and supersedes any declaration issued previously for the same product.

**Signed for on behalf of: SCHILLER AG**

Date of Issue: 16.03.2021  
 Place of Issue: Baar, Switzerland

  
 Eckard Glaser  
 Head of Quality Management


  
 Valentina Shcherba  
 Head of Regulatory Affairs

	<b>Declaration of Conformity</b>		<b>SCHILLER</b> The Art of Diagnostics
	CH-DHF-2543 Rev. 02	Effective Date : 16 Mar 2021	

### Appendix 01 Accessories/devices Compatible to the Device Covered by This Declaration

SCHILLER AG REF Number	Accessory/Device Name	Legal Manufacturer
2.100325	Velcro plaster (x10)	SCHILLER AG
2.120055	Fixation flap for BP cuffs	Ergosana GmbH
2.120077	BP cuff D-Ring size M,	SCHILLER AG
2.120080	BP cuff D-Ring, size S, BR-102 plus, BP-200 plus	SCHILLER AG
2.120081	BP cuff D-Ring, size M, BR-102 plus, BP-200 plus	SCHILLER AG
2.120082	BP cuff D-Ring, size L, BR-102 plus, BP-200 plus	SCHILLER AG
2.310249	QRS trigger cable to CS-200 Touch	SCHILLER AG
4.520562	QRS trigger cable to CS-200 / AT-10 / CS-100 / AT-60	SCHILLER AG
4.520563	QRS trigger cable to AT-110 / PT-160	SCHILLER AG
4.520564	QRS trigger cable to AT-10 plus/CS-200 Excellence/AT-170	SCHILLER AG
2.100006	Stereo Bügelkopfhörer BP-200+/ Headphone	SCHILLER AG
2.100326	Mik Pflaster BR-102/plus 10x/ Headphone plaster	SCHILLER AG
2.100582	LNCS Adult TCI SPO2 Ohrsensor/ear sensor	Masimo Corp. USA
2.120075	Mikroph & Schlauch 14 BP-200+/microphone and tube	Ergosana GmbH
2.200109	Netzteil BP-200 plus/ power adapter	GlobTek Inc.
2.200119	Akku BR-102plus, BP-200plus	SCHILLER AG
2.200179	Ladegerät BR-102 plus, BP-200p/ charger	HyLine AG
2.300003	3P 2.5m Netzkabel CH, 1x abgew./ power supply angled	Queen Puo Electric Co. LTD
2.300004	3P 2.5m Netzkabel UK, 2x abgew./ power supply angled	Queen Puo Electric Co. LTD
2.300005	3P 2.5m Netzkabel D, 2x abgew. / power supply angled	Queen Puo Electric Co. LTD
2.300014	3P 2.5m Netzkabel CN, abgew./ power supply angled	Queen Puo Electric Co. LTD
2.300016	3P 2.5m Netzkab. Japan 1xabge/ power supply angled	Queen Puo Electric Co. LTD
2.300024	3P 2.5m Netzkabel HG US, 1xabge/ power supply angled	Queen Puo Electric Co. LTD
2.300025	3P Netzkabel Brasilien, 1x abge/ power supply angled	Queen Puo Electric Co. LTD
2.310228	LP SpO2 Kabel Masimo LNCS 3.0m	SCHILLER AG
4.520373	RS-Verb.kabel BP-200/200plus/ connector cable	SCHILLER AG



	<b>Declaration of Conformity</b>		<b>SCHILLER</b> <small>The Art of Diagnostics</small>
	CH-DHF-2543 Rev. 02	Effective Date : 16 Mar 2021	

**Device Dependent Declaration of Conformity Revision History**

Brief Description of Change	Version	Release Date
First version on MC (signed 02.04.2019)	01	Ref. MC Release Date
Based on TMPL-0085 04 Updated accessories list see CR-0386 First CE marking (informative): 2006	02	Ref MC Release date