



EU Declaration of Conformity (MDD)

Effective Date : 21.07.2021

SCHILLER
The Art of Diagnostics

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	SPIROVIT SP-1 G2		
Product Type	Spirometer		
Intended Purpose	The SPIROVIT SP-1 G2, together with the sensor SpiroScout SP plus, is a stand-alone diagnostic system for basic examination of the lung function. The system is also intended for monitoring the course of diseases and for therapy control during treatment.		
Risk Class acc. to Annex IX MDD	IIa		
GMDN Code	13680 (Diagnostic spirometer)		
REF Number	REF #	GTIN	Description
	3.911120 (part of 0A.500000)	07613365002881	SPIROVIT SP-1 G2 (base device)
System Version	System: 1.0.0 Hardware: 01.00.00 Software: 1.0.0		
Standards Applied	EN ISO 13485:2016 EN 60601-1:2006/A1:2013 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) EN 62366:2008 (IEC 62366-1:2015) EN 60601-1-6:2010 (IEC 60601-1-6:2010 +AMD:2013) EN ISO 14971:2012, ISO 14971:2019 EN 62304:2006/AC:2008 (IEC 62304:2006+AMD1:2015) EN ISO 26782:2009 (ISO 26782:2009) EN ISO 23747:2009 (ISO 23747:2015) EN ISO 15223-1:2016 EN 1041:2008+A1:2013 MEDDEV 2.7.1 rev.4 ERS/ATS-Spirometry-Standard 2017		

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.



EU Declaration of Conformity (MDD)

Effective Date : 21.07.2021

SCHILLER
The Art of Diagnostics

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



EU Declaration of Conformity (MDD)

Effective Date : 21.07.2021

SCHILLER
The Art of Diagnostics

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
1.500041	SpiroScout SP plus (incl. USB cable, ScoutTube 50 pieces and nose clips 50 pieces) (04 421 0020)	04 421 0020	Ganshorn Medizin Elektronik GmbH
2.101123	ScoutTube (package with 50 pieces) (01 942 0620)	01 942 0620	Ganshorn Medizin Elektronik GmbH
2.101187	Nose clip (package with 50 pieces) (A508 / MAF-TDS-261) GME REF: 01 941 0906	A508 / MAF-TDS-261	GVS Filter Technology UK Ltd.
2.157054	Thermal chart paper, 1 roll (minimum order quantity is 10 rolls, this article must be ordered by multiples of 10) (0167849.008)	0167849.008	Diagramma AG
2.100219	Calibration syringe 3 litres (9544.100C)	9544.100C	Sotax AG
2.101188	Adaptor for calibration syringe	n/a	Rogenmoser Feinmechanik AG
2.160016	Dust cover (JT TECH REF4.430181)	4.430181	JT tech Electronics
2.101124	Trolley for SPIROVIT SP-1 G2	n/a	Multix Solutions s.r.l.
2.101159	Bracket for SpiroScout SP plus (to fit trolley 2.101124) (SCHILLER_SSSP+_X4)	SCHILLER_SSSP+_X4	Multix Solutions s.r.l.
2.300000	Mains cable CH, straight, 2.5 m (QP022+QP007 H05VV-F 3G)	QP022+QP007H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300002	Mains cable D, straight, 2.5 m (QP004+QP007 H05VV-F 3G)	S03 ST3 H05VV-F 3G1.00MM ² 2.5M GREY	Ningbo Ousheng Electric Co., Ltd
2.300003	Mains cable CH, 90° angled, 2.5 m (QP022+QP018 H05VV-F 3G)	QP022+QP018 H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300004	Mains cable UK, 90° angled, 2.5 m (QP026(10A)+QP018 H05VV-F 3G)	QP026(10A)+QP018 H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300005	Mains cable D, 90° angled, 2.5 m (QP004+QP018 H05VV-F 3G)	QP004 +QP018H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300011	Mains cable UK, straight, 2.5 m (QP026(13A)+QP007 H05VV-F 3G)	QP026(13A)QP007H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300012	Mains cable US hospital grade, straight, 2.5 m (QP049+QC-01 SJT 3C 18AWG 105D)	QP049HG+QC-01SJT3AWG18GR2500	Queen Puo Electric Co. LTD
2.300014	Mains cable China, 90° angled, 2.5 m (QP012+QP018 H05VV-F 3G)	QP012+QP018 H05VV-F3G1.025M RAL7035	Queen Puo Electric Co. LTD
2.300016	Mains cable Japan, 90° angled, 2.5 m (QP005+QP007 VCTF 3G)	QP005+QP007VCTF3G0.75GR2500	Queen Puo Electric Co. LTD
2.300024	Mains cable US hospital grade, 90° angled, 2.5 m	QP049HG+QP018SJT3AWG18GR2500	Queen Puo Electric Co. LTD



EU Declaration of Conformity (MDD)

SCHILLER
The Art of Diagnostics

Effective Date : 21.07.2021

	(QP049+QP018 SJT 3C 18AWG 105D)		
2.300025	Mains cable Brazil, 90° angled, 2.5 m (QP084+QP018 H05VV-F 3G)	QP084+QP018H05VV-F3G1GR2500	Queen Puo Electric Co. LTD



EU Declaration of Conformity (MDD)

Effective Date : 21.07.2021

SCHILLER
The Art of Diagnostics

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First introduce to CE-mark region 18.05.2021 Based on TMPL-0085 Rev. 04 (first version in Confluence)	01	2021-05-25
Update to TMPL-0085 Rev.06	02	2021-07-21