



# EU Declaration of Conformity (MDD)

**SCHILLER**  
The Art of Diagnostics

CH-DHF-0746 Rev. 05

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			
<b>Trade Name</b>	EASY PULSE		
<b>Product Type</b>	Cardiopulmonary Resuscitation Device		
<b>Intended Purpose</b>	<p>The Easy Pulse is an active therapeutic device intended to do automatic multidirectional chest compression.</p> <p>The device may be used in the following situations:</p> <ul style="list-style-type: none"> <li>- Primary rescue</li> <li>- Secondary rescue</li> </ul> <p>Stationary on emergency wards, in cardiological intensive care units and operating theatres</p>		
<b>Risk Class acc. to Annex IX MDD</b>	IIb		
<b>GMDN Code</b>	61908		
<b>REF Number</b>	<b>REF #</b>	<b>GTIN</b>	<b>Description</b>
	3.940409	07613365001853	EASY PULSE (IP43 with protective)
	3.940410 (part of 0A.400000)	07613365001679	EASY PULSE (main device)
<b>Standards Applied</b>	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012) EN 60601-1-2:2015 (IEC 60601-1-2:2014) IEC 60601-1-12:2014 EN 60601-1-6:2010 (IEC 60601-1-6:2010/A1:2013) IEC 62366:2007/A1: 2014 EN 62304:2006 (IEC 62304:2006/A1:2015) BS EN 1789: 2020 (replaces EN 1789:2007+A1:2010+A2:2014) EN ISO 10993-1:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2014 EN ISO 15523-1:2016 EN ISO 1041:2008+A1:2013 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
2.101105	Punch top EASY PULSE, single use, set of 10 pcs	See SCHILLER AG REF No.	SCHILLER AG
2.310148	DC-in cable open-end EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
2.100857	Slider complete EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
2.156093	Transportation bag EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
2.200123	Medical mains part 24V 6.25A 100- 240V for charging station 2.200190	4000-DT150MED/24	FRIWO
2.200124	Medical power supply unit 48V/400W, 100-240V for EASY PULSE	PMP400-18-S, K1	PROTEK
2.200190	Charging station EASY PULSE	103686	TEFAG
2.310149	USB cable EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
4.120175	Replacement belt for slider EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
4.350049	Li-Ion battery EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
4.430236	Bellows with Velcro fastener EASY PULSE	See SCHILLER AG REF No.	SCHILLER AG
4.430373	Silicone Loop	BZ-9020 SI	ZWAHLEN



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## Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First introduce to CE-mark region (11.08.2016 version resigned 26.08.2016)	01	11.08.2016
Update to MC TMPL	02	See MC Release Date
Update EN ISO 10993-10: 2014, 10993-5: 2009	03	See MC Release Date
Update Standards with titles, addition of harmonized standards to already mentioned standards IEC, addition of EN 1789, 15223, 1041	04	See MC Release Date
Update to TMPL-0085 Rev.06 Removed the standard's title (e.g. from EN ISO 13485: 2016: Medical devices – Quality management to EN ISO 13485: 2016) Changed SAG to SCHILLER AG Referenced harmonized standards	05	2021-07-21