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	EASY PULSE		
Product Type	Cardiopulmonary Resuscitation Device		
Intended Purpose	The Easy Pulse is an active therapeutic device intended to do automatic multidirectional chest compression. The device may be used in the following situations: - Primary rescue - Secondary rescue Stationary on emergency wards, in cardiological intensive care units and operating theatres		
Risk Class acc. to Annex IX MDD	IIb		
GMDN Code	61908		
REF Number	REF #	GTIN	Description
	3.940409	07613365001853	EASY PULSE (IP43 with protective)
	3.940410 (part of 0A.400000)	07613365001679	EASY PULSE (main device)
Standards Applied	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.

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.

CE 0123

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

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

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