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	FRED easyport plus®		
Product Type	Automated-External defibrillator (AED)		
Intended Purpose	The FRED easyport plus® is a defibrillator with the possibility to deliver a shock in semi-automatic, fully automatic or manual mode. FRED easyport plus® is intended to be used to terminate cardiac arrhythmia such as Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT) with a defibrillation shock. The intended patient population are adults and children weighing less than 25 kg (younger than 8 years of age). Following people may us the FRED easyport plus®: • Layperson trained in Basic Life Support and/or on the device • Healthcare provider trained in Basic Life Support and/or on the device • Physicians or other healthcare provider trained in Advanced Life Support may use the FRED easyport plus® with manual override The device must not be used if the patient is responsive, breathing and has a pulse.		
Risk Class acc. to Annex IX MDD	IIb		
GMDN Code	48048 (Rechargeable professional automated external defibrillator) 48049 (Non-rechargeable professional semi-automated external defibrillator)		
REF Number	REF #	GTIN	Description
	3.940060 (part of 0A.900000)	07613365001921	FRED Easyport plus AED First
	3.940063 (part of 0A.900000)	07613365002621	FRED Easyport plus AED AUTO
	3.940066 (part of 0A.900000)	07613365002652	FRED Easyport plus AED MANUAL
Standards Applied	EN ISO 13485: 2016 EN ISO 14971:2012 EN 60601-1:2006/A1:2013 (IEC 60601-1: 2012) EN 60601-1-2:2015 (IEC 60601-1-2: 2014) EN 60601-1-6:2010 (IEC 60601-1-6:2010+AMD1:2013) EN 60601-1-8:2007 (IEC 60601-1-8:2006/AMD1:2012) IEC 62366-1:2015/COR1:2016 EN 60601-1-11:2015 (IEC 60601-1-11: 2015) EN 60601-1-12:2015 (IEC 60601-1-12: 2014) EN 60601-2-4:2011 (IEC 60601-2-4: 2018)		

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 and Appendix 02 for spare parts and components.

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.

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*.

Signed for on behalf of: SCHILLER AG

Date of Issue: 2022-10-18
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY MANAGEMENT

Signature

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

Name: VALENTINA SHCHERBA

Title / Function: HEAD OF REGULATORY AFFAIRS

Signature

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

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
2.100519	Securing Pads (5x) (for CPR Feedback Sensor)	See SCHILLER AG REF No.	SCHILLER AG
2.100860	ARGUS LifePoint (CPR Feedback Sensor)	See SCHILLER AG REF No.	SCHILLER AG
2.100870	ARGUS LifePoint 2 (CPR Feedback Sensor hourglass-shaped)	See SCHILLER AG REF No.	SCHILLER AG
2.155061	Defibrillation Electrode Pads Adult (wire in)	See SCHILLER AG REF No.	Leonhard Lang GmbH (MDR Class I)
2.155065	Defibrillation Electrode Pads Adult (wire out)	See SCHILLER AG REF No.	Leonhard Lang GmbH (MDR Class I)
2.155067	Defibrillation Electrode Pads Paediatric (wire in)	See SCHILLER AG REF No.	Leonhard Lang GmbH (MDR Class I)
2.230377	Defibrillation Electrode Pads Adult RFID (wire out)	0-21-0040	Leonhard Lang GmbH (MDR Class I)

Appendix 02 spare parts and components compatible to the device(s) covered by this declaration:

SCHILLER AG REF No.	Accessory/Device name	REF No. as per Label	Legal Manufacturer
2.156095	Carrying Bag red	See SCHILLER AG REF No.	Halfar
2.200133	Power Supply for Schiller BT Bridge	GSM12E05-USB	Mean Well
2.200146	Power Supply for Battery Charger CS-2	FSP065M-DAA	FSP Technology Inc
2.200191	Battery Charger CS-2	See SCHILLER AG REF No.	SCHILLER AG
2.300000	Power cord CH straight	QP022 +QP007H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.300002	Power cord SCHUKO straight	S03 ST3 H05VV-F 3G1.00MM 2.5M	OUSHENG
2.300011	Power cord UK straight	QP026 (13A) QP007H05VV-F3G1GR2500	Queen Puo Electric Co. LTD
2.310420	USB A 90-90 Adapter	See SCHILLER AG REF No.	SCHILLER AG
2.610066	USB cable for Power Supply	46800	Goobay
3.940070	Schiller BT Bridge	See SCHILLER AG REF No.	SCHILLER AG
4.350062	AccuPack Li-Ion (3ICP34/50)	See SCHILLER AG REF No.	SCHILLER AG
4.350063	BatteryPack $LiMnO_2$(4CR123A)	See SCHILLER AG REF No.	SCHILLER AG

Device Dependent Declaration of Conformity Revision History

All approvals are maintained and controlled in the Document Management System 'Confluence'. Please refer to Confluence for the full approval record.

Brief Description of Change	Version	Release Date
First revision in MasterControl® (only FEP200J First)	01	See effective date in MasterControl®
- Migration to new TMPL - Remove GMDN for public Adding accessories	02	See effective date
- Will be released with product release risk assessment – pandemic TMPL-0090 - Adding variants -63/-66 - Adding auto, manual to intended use, amending intended use with user, patient, contraindication - Change in biocomp. Year specification - Comment: EN1789 not added since part of -1-12	03	See effective date
- Biocomp deleted (main device is not intended to have direct patient contact) - Typo corrected from 2.200149 to 2.200146 - Adapted to TMPL-0085 04	04	See effective date
Update to TMPL-0085 Rev.06 Referenced harmonized standard	05	2021-07-21
- Update for system 1.2.1 (removed this section from first table) - Split appendix table into accessories and spare parts	06	2021-09-22
- Update for system 1.2.3ff. - Added IEC 60601-1-8 to applied standards - Amended IEC 60601-1 with A1:2013 - Amended IEC 62366-1 with COR1 - Aligned GMDN with available batteries (added 48048) incl. addition of explanatory text to GMDN - Added Note to Device Dependent Revision History (reference to Confluence) - Amended "Accessory/device names" in Appendix 01 (editorial) - Adapted IEC 60601-2-4 from IEC 60601-2-4:2010 to IEC 60601-2-4:2018 - Moved RoHS section below CE_{0123}-marking relevant for MD	07	2022-10-18