CARDIOVIT AT-180
EU MDR Declaration of Conformity
Rev. 01

SCHILLER
The Art of Diagnostics

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland
SRN: CH-MF-000012722

EU Authorised Representative: SCHILLER Medizintechnik GmbH
Otto-Lilienthal-Ring 4, 85622 Feldkirchen, Germany
SRN: DE-AR-000006934

QMS: Q5 041505 0115

EC-certificate: G10 041505 0132

Notified Body: TÜV SÜD Product Service GmbH, ID 0123

Device Information				
Trade Name	CARDIOVIT AT-180			
Product Type	Electrocardiograph			
Intended Purpose	The CARDIOVIT AT-180 is an electrocardiograph intended to be used by trained operators under the direct supervision of a licensed physician in healthcare facilities to acquire ECG signals from body surface electrodes, record, analyse, display and print ECGs to support diagnosis of cardiovascular diseases in adult and paediatric patients at rest or undergoing exercise stress testing.			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	16231			
EMDN Code	Z120503			
Basic UDI-DI	76133650000000085A			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name	Date added
	3.920570 (part of 0A.110000)	07613365002775	CARDIOVIT AT-180	2025-02-06
Standards Applied and Common Specifications	ISO 13485:2016 (EN ISO 13485:2016 + AC:2018 + A11:2021) ISO 14971:2019 (EN ISO 14971:2019 + A11:2021) IEC 60601-1:2020 (EN 60601-1:2015 + A1:2021) IEC 60601-1-2:2020 (EN 60601-1-2:2015 + A1:2021) IEC 60601-2-25:2011 (EN 60601-2-25:2015) IEC 62304:2015 (EN 62304:2006 + Cor.:2008 + A1:2015) IEC 62366-1:2020 (EN 62366-1:2015 + AC:2015 + A1:2020) IEC 60601-1-6:2020 (EN 60601-1-6:2010 + A1:2015 + A2:2021) ISO 20417:2021 ISO 15223-1:2021 (EN ISO 15223-1:2021) ISO 17664-2:2021			

We, the undersigned, declare that the medical device described above is in conformity with the applicable provision of the *MDR (EU) 2017/745: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,* amending *Directive 2001/83/EC, Regulation (EC) No 178/2002* and *Regulation (EC) No 1223/2009* and repealing *Council Directives 90/385/EEC and 93/42/EEC*

The products are CE marked with notified body number.

CE 0123

RoHS 2 and 3

We, the undersigned, further declare that the medical device described above is in conformity with the applicable provision of the *Directive 2011/65/EU "Restriction of the use of certain hazardous substances in electrical and electronic equipment"* and its *amended Directive 2015/863/EU.*

This declaration of conformity is issued under the sole responsibility of SCHILLER AG. This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of **SCHILLER AG**

Date of Issue: 2025-02-06
Place of Issue: Baar, Switzerland

Name: Stefan Bigler	Name: Aynur Aslanova
Title / Function: Head of Regulatory Affairs	Title / Function: Head of Quality Management
Signature	Signature

Appendix 01 List of compatible medical devices and accessories covered by this declaration

SCHILLER AG REF No.	Device name	REF No. as per Label	Legal Manufacturer
2.400180	ECG D-SUB B 3.1/2.55 x10 IEC	see SCHILLER AG REF No.	SCHILLER AG
2.400179	ECG D-SUB B 3.1/2.55 x10 AHA	see SCHILLER AG REF No.	SCHILLER AG
2.400175	ECG D-SUB C 4.6/4.25 x10 IEC	see SCHILLER AG REF No.	SCHILLER AG
2.400178	ECG D-SUB C 4.6/4.25 x10 AHA	see SCHILLER AG REF No.	SCHILLER AG
2.400139	ECG D-SUB C 3.5/3.15 x14 AHA	see SCHILLER AG REF No.	SCHILLER AG
2.400140	ECG D-SUB C 3.5/3.15 x14 IEC	see SCHILLER AG REF No.	SCHILLER AG
2.400141	ECG D-SUB B 3.5/3.15 x14 AHA	see SCHILLER AG REF No.	SCHILLER AG
2.400142	ECG D-SUB B 3.5/3.15 x14 IEC	see SCHILLER AG REF No.	SCHILLER AG
2.410099	ECG EL-LT C 1.3/0.78 x4 IEC	see SCHILLER AG REF No.	SCHILLER AG
2.410090	ECG EL-LT B 1.3/0.78 x4 IEC	see SCHILLER AG REF No.	SCHILLER AG

Appendix 02 List of compatible non-medical device(s), spare parts, and components covered by this declaration

SCHILLER AG REF No.	Description / Device name
2.300000	Line cord, CH
2.300002	Line cord, D
2.300003	Line cord CH, angled
2.300004	Line cord UK, angled
2.300005	Line cord D, angled
2.300011	Line cord, UK
2.300012	Line cord HG, USA
2.300014	Line cord, China, angled
2.300016	Line cord Japan
2.300024	Line cord HU US, angled
2.300025	Line cord, Brasil
2.000147	Barcode Scanner Set
2.310005	Potential equalization cable 5m

Change History

Description of Change	Revision
First version	01