



FT-1 RED Declaration of Conformity

SCHILLER
The Art of Diagnostics

Manufacturer: SCHILLER AG
Altgasse 68, 6341 Baar, Switzerland

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

Radio Equipment:			
Trade Name	CARDIOVIT FT-1		
Product Type	Electrocardiograph		
Conformity Assessment	Modul A (Annex II of the RED, internal production control)		
REF Number	REF #	GTIN	Description
	3.900860	07613365000184	CARDIOVIT FT-1 (HW1)
	3.900863 (part of 0A.106000)	07613365002867	CARDIOVIT FT-1 (2018)
	3.900864 (part of 1A.106300)	07613365002003	CARDIOVIT FT-1 CRO (CRO HW1)
	3.900865 (part of 1A.106400)	07613365003642	CARDIOVIT FT-1 CRO (CRO 2018)
	3.900870 (part of 0A.106500)	07613365003284	CardioPad-2 (SECA, base device FT-1 2018)
System numbers (System/hardware/software)	System: 2.1.x* Software: 2.1.x* Hardware: 2.0.x*		
Standards Applied	HEALTH & SAFETY (Art. 3.1(a)) IEC 60601-1: 2020 IEC 62368-1: 2014 EMC (Art. 3.1(b)) IEC 60601-1-2: 2020 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.1.1 EN 62311: 2008 RADIO SPECTRUM (Art. 3(2)) ETSI EN 300 328 v2.2.2 ETSI EN 301 893 V2.1.1		

*x is a placeholder for version number for patches / bug fixes without affecting product conformity

We, hereby declare, under our sole responsibility that the radio equipment listed above to which this declaration relates, is in conformity with technical requirements of the standards listed above and the provisions of the essential requirements of the Radio Equipment Directive 2014/53/EU.

This declaration supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 2022-07-21
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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Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First version	01	2022-07-21