FT-2 RED Declaration of Conformity
Rev. 01

SCHILLER
The Art of Diagnostics

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

Radio Equipment:	
Trade Name	CARDIOVIT FT-2
Product Type	Electrocardiograph
Conformity Assessment	Modul A (Annex II of the RED, internal production control)
REF Number	3.900880 - CARDIOVIT FT-2 3.900890 - CARDIOVIT FT-2 / TP
Standards Applied	HEALTH & SAFETY (Art. 3.1(a)) EN IEC 60601-1: 2020 EMC (Art. 3.1(b)) EN IEC 60601-1-2: 2020 ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.1.1 RADIO SPECTRUM (Art. 3(2)) ETSI EN 300 328 V2.2.2 ETSI EN 301 893 V2.1.1

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: January 10, 2024
Place of Issue: Baar, Switzerland

Name: ECKARD GLASER

Title / Function: HEAD OF QUALITY MANAGEMENT

Signature

Name: STEFAN BIGLER

Title / Function: HEAD OF REGULATORY AFFAIRS

Signature

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Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Revision	Release Date
First version	01	2024-01-10