medilogFD
RED Declaration of Conformity
Rev. 01

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

RED	
Trade Name	medilogFD
Product Type	0203 (Non-Invasive) ECG Holter Recorder
Conformity Assessment	Module A (Annex II of the RED, internal production control)
REF Number	3.900491 (part of 0A.304000)
Standards Applied	HEALTH & SAFETY (Art. 3.1(a)) IEC 60601-1:2020 (EN 60601-1:2015 + A1:2021) IEC 62368-1: 2014 (2. Ed.)/Cor.1:2015 and EN 62368-1: 2014/AC: 2015/A11: 2017 EMC (Art. 3.1(b)) IEC 60601-1-2:2020 (EN 60601-1-2:2015 + A1:2021) ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-17 V3.2.4 RADIO SPECTRUM (Art. 3(2)) EN 300 328 V2.2.2

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: 2024-11-25
Place of Issue: Baar, Switzerland

Name: AYNUR ASLANOVA

Title / Function: HEAD OF QUALITY MANAGEMENT

Signature

Name: STEFAN BIGLER

Title / Function: HEAD OF REGULATORY AFFAIRS

Signature

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

Device Dependent Declaration of Conformity Revision History

Brief Description of Change	Version	Release Date
First version	01	2024-11-25