



**medilogFD**  
**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	medilogFD			
Product Type	0203 (Non-Invasive) ECG Holter Recorder			
Intended Purpose	<p>The medilogFD is an ambulatory ECG recorder intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities or home environment to acquire, digitize, wirelessly transmit and store data of up to a 12 lead ECG for a measuring duration of an extended period of 24 hours or more including the detection of pacemaker pulses, presence of p-waves and R-peaks as well as the ECG derived respiration (EDR) to help user making a diagnosis in adult and paediatric patients above 2 years of age and with a body weight of over 10kg (22lbs). The ability to stream ECG with diagnostic bandwidth is intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities to acquire ECG signals from body surface electrodes and wirelessly transmit ECG snapshots during an ambulatory ECG recording to a host device to help user in making a diagnosis in adult and paediatric patients above 2 years of age and with a body weight of over 10kg (22lbs).</p> <p>The medilogFD can be connected with other medical devices (e.g. SpO2 sensor, blood pressure measurement devices) using the Bluetooth® module.</p>			
Risk Class acc. to Annex VIII MDR	IIa			
GMDN Code	35162			
EMDN Code	Z120504			
Basic UDI-DI	761336500000002254			
Conformity Assessment acc. to MDR	Annex IX Chapters I and III			
REF Number	REF #	GTIN	Device Name	Date added
	3.900491 (part of 0A.304000)	07613365004007	medilogFD	2024-11-25
Serial Numbers	3040.XXXXXX			



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<b>Standards Applied and Common Specifications</b>	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 60601-1-11:2020 (EN 60601-1-11:2015 + A1:2021) IEC 60601-2-47:2012 (EN 60601-2-47:2015) IEC 62304:2015 (EN 62304:2006/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 10993-1:2018 (EN ISO 10993-1:2020) ISO 15223-1:2021 (EN ISO 15223-1:2021)
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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.



**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: 2024-11-25

Place of Issue: Baar, Switzerland

Name: AYNUR ASLANOVA

Name: STEFAN BIGLER

Title / Function: HEAD OF QUALITY  
MANAGEMENT

Title / Function: HEAD OF REGULATORY  
AFFAIRS

Signature

**SCHILLER AG**  
Altgasse 68  
4-8341 Baar/Switzerland

Signature



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

SCHILLER AG REF No.	Description / Device name	GTIN/EAN (if available)
2.400183	ECG BWDSC P 0.82 x10 IEC (MD-spare parts) 10-wire patient cable IEC snap-button 0.8 meters (2.6 feet), medilogFD	07613365003581
2.400189	ECG BWDSC P 0.82 x10 AHA (MD-spare parts) 10-wire patient cable AHA snap-button 0.8 meters (2.6 feet), medilogFD	07613365003987
2.310428	USB cable, USB Type-A to USB-C	-
2.100850	Alkaline battery LR03, type AAA, 1.5V	-
2.610078	microSD card	-
2.200133	Power supply, 5V/12W, USB Type-A (EU)	-
2.200137	Power supply, 5V/12W, USB Type-A (US)	-
2.156096	medilogAR Neck Belt	-
2.156086	Holter pouch single use	-
4.310735	Battery cover (Batteriedeckel MS-12 BT)	-
4.435414	Carrying case	-

**Change History**

Description of Change	Revision
First version	01