



**FRED easyport plus TRAINER
RED Declaration of Conformity**

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	FRED easyport plus TRAINER
Product Type	Training device
Conformity Assessment	Modul A (Annex II of the RED, internal production control)
REF Number	3.940069 (part of 1A.901000)
Software version	1.2.x*
Standards Applied	<p>HEALTH & SAFETY (Art. 3.1(a)) IEC 60601-1:2005+AMD1:2012 IEC 62368-1:2014</p> <p>EMC (Art. 3.1(b)) EN 60601-1-2: 2014 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 62311:2008</p> <p>RADIO SPECTRUM (Art. 3(2)) EN 300 328 v2.2.2</p>

*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.

The products are CE marked without 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 supersedes any declaration issued previously for the same product.

Signed for on behalf of: SCHILLER AG

Date of Issue: 10 February 2023
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	Version	Release Date
First version	01	2023-02-10