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EU DECLARATION OF CONFORMITY WITH DIRECTIVE 2014/53/EU

File N° : CE ARE 0134

PRODUCT

Name : FRED PA-1 Trainer

Function : Simulator of the defibrillator FRED PA-1 for training

Number : **Composition of the number 13499asxxxx**

a : Last number of the year of manufacture

s : Device serial number

xxxx : Unit number

MANUFACTURER

Address of the manufacturer: SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg

PROOF OF CONFORMITY WITH MAIN REQUIREMENTS WITH DIRECTIVE USED

Directive 2014/53/UE

Standards for EMC: EN 61000-6-1 EN 61000-6-3 EN 55032

ETSI EN 301 489-1 v2.1.1

ETSI EN 301 489-17 v3.1.1

Standards for Radio :

EN 62311

ETSI EN 300 328 v2.1.1

Standard for electrical Safety:

IEC 61010-1 (EN 61010-1)

ENGAGEMENT

This declaration of conformity is issued under the sole responsibility of the manufacturer.

As responsible for Regulatory Affairs at SCHILLER MEDICAL, I hereby certify that:

- The product above fulfils the main requirements set out in Directive 2014/53/UE, Article 3.
- CE labelling will be fixed in accordance with directive used.

Wissembourg, July 08, 2020.

SCHILLER MEDICAL

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Valérie ENGEL
Regulatory Affairs manager



THE ART OF DIAGNOSTICS