SCHILLER MEDICAL
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Declaration of conformity with directives 93/42/CEE and 2014/53/UE

File N°: CE ARE 0127

Product

Name: **FRED PA-1**
Function: **Semi-automated or automated external defibrillator for Public access (PAD)**

Classification: **IIb** in accordance with rule 9 below of classification of medical device of Directive 93/42/CEE

"All active therapeutics devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, density and site of application of the energy, in which case they are in Class IIb.
All active devices intended to control or monitor the performance of active therapeutic device in Class IIb, or intended directly to influence the performance of such devices are in Class IIb."

Number: **Composition of number 12799sxxxxxx**
127 : project number of the device
12799: FRED PA-1
s : device serial number
xxxxxx : Unit number

Manufacturer:

Manufacturer's address: SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

Standards applied

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-6
IEC 60601-1-11
IEC 60601-2-4

Notified Body

Number: 0459
Name: GMED
Address: 1, rue Gaston Boissier 75724 PARIS CEDEX 15-France

THE ART OF DIAGNOSTICS

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PROOF OF CONFORMITY WITH MAIN REQUIREMENTS WITH DIRECTIVES USED

Directive 93/42/CEE
Annex II: GMED certificate CE n° 23246 rev 9 issued on April 21 h, 2021

Directive 2014/53/UE
Standards applied
-Safety and health (ART 3.1.a): serial IEC 60601
- CEM (ART 3 .1b) : IEC 60601-1-2
- Spectrum (ART 3.2) : ETSI EN 302 291-1 V1.1.1
ETSI EN 302 291-2 V1.1.1
ETSI EN 301 489 -1 v1.9.2
ETSI EN 301 489 -3 v1.6.1
ETSI EN 301 908-1 V11.1.1
ETSI EN 300 330 v2.1.1
ETSI EN 301 489-1v2.1.1
ETSI EN 301 489-3 v2.1.0
ETSI EN 301 489-24 v1.5.1

ENGAGEMENT

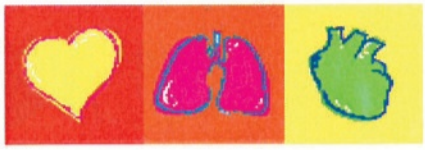
As responsible for Regulatory Affairs at Schiller MEDICAL, I hereby certify that :

- The product above fulfils the main requirements set out in Directive 93/42/CEE appendix I, chapter 1 to 13
- The product above fulfils the main requirements set out in Directive 2014/53/UE
- CE labelling will be fixed in accordance with directives used.

Wissembourg, May 06, 2021

[redacted] R MEDICAL
uis Pasteur
BOURG | FRANCE
3 88 63 36 00

Valérie ENGEL
Regulatory Affairs manager



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