SCHILLER MEDICAL
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Internet : http://www.schiller-medical.com
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MEDICAL

Declaration of conformity with directive 93/42/CEE

File N°: CE ARE 0031

Product

Name: **FRED easy French fireman**
FRED easy DSA (SD card)
FRED easy DSA (Ethernet)
FRED easy DSA Manuel (SD card)
FRED easy DSA Manuel (Ethernet)
FRED easy DA (SD card)
FRED easy DA (Ethernet)
FRED easy Life DSA (SD card)
FRED easy Life DA (Ethernet)
FRED easy Life DA (SD card)
FRED easy Life DSA (Ethernet)
FRED easy Online

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 the number 058vvsxxxxxx**
058 : project number of the device
05899: Fred easy SD card family
05893: Fred easy Ethernet/ online family
05895: Fred easy Life SD card family
05896: Fred easy Life Ethernet/online family
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 60601-2-4
IEC 60601-1-12

THE ART OF DIAGNOSTICS

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SCHILLER
MEDICAL

Notified Body

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

PROOF OF CONFORMITY WITH MAIN REQUIREMENTS WITH DIRECTIVE USED

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

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
- CE labelling will be fixed in accordance with directive 93/42/CEE

Wissembourg , May 06, 2021

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Valerie ENGEL
Regulatory Affairs manager