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## 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 058vvsxxxxx**  
**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**  
**xxxxx : Unit number**

### Manufacturer:

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

### Standards applied

IEC 60601-1  
IEC 60601-1-6  
IEC 60601-1-12  
IEC 60601-1-2  
IEC 60601-2-4



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## 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 :

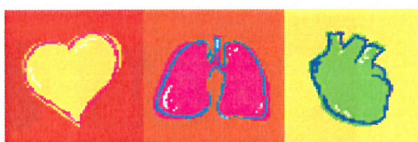
- The product above fulfils the main requirements set out in Directive 93/42/CEE appendix I , chapter 1 to 13
- CE labelling will be fixed in accordance with directive 93/42/CEE

Wissembourg , May 06, 2021

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Valerie ENGEL  
Regulatory Affairs manager



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