SCHILLER MEDICAL
BP 90050
4, rue Louis Pasteur
67162 Wissembourg Cedex
FRANCE

SCHILLER
MEDICAL S.A.S.

DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42/EEC

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 devices of Directive 93/42/EEC:

"All active therapeutic 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, the 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 devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb."

Number: **composition of number: 12799asxxxxx**

12799	: FRED PA-1
a	: Last number of the year of manufacturing
s	: Device serial number
xxxxx	: Unit number

The Art of Diagnostics

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MEDICAL S.A.S.

MANUFACTURER

Manufacturer's address: **SCHILLER MEDICAL**
4, rue Louis Pasteur
67162 WISSEMBOURG CEDEX FRANCE

NOTIFIED BODY

Number : **0459**
Name : **LNE / G-MED**
Address : **1, rue Gaston Boissier**
75724 PARIS Cedex 15 - FRANCE

PROOF OF CONFORMITY WITH MAIN REQUIREMENTS OF DIRECTIVE 93/42/EEC USED

Annex II section 3: LNE/G-MED certificate CE N° 23246 rev. 3 issued on August 22, 2016

ENGAGEMENT

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

- The product defined above fulfils the main requirements set out in Directive 93/42/EEC Appendix I chapters 1 to 13.
- CE labelling will be affixed in accordance with Article 17 of Directive 93/42/EEC.

Wissembourg, May 10, 2017

SCHILLER MEDICAL
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Court GOEHRY
Regulatory Affairs Manager

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