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## LABELLING

### RESCUE LIFE

Code: TF-RescueLife-2.0/3.2-0.2

| STATE OF REVISIONS |                                                                                   |             | APPROVED BY:                                                                                      |
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| Rev N.             | Reason                                                                            | Date        | Dr. Cesare Mangone – President & CEO                                                              |
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| 0.1                | Translation to english language                                                   | 2019, March |                                                                                                   |
| 0.0                | Renewal certification                                                             | 2018, April |                                                                                                   |

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## Summary

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## 1. Reference standard

Symbols adopted in labels are in accordance with the following harmonized standards:

- **UNI CEI EN 1041:2013** “Information provided by the manufacturer of medical devices”;
- **UNI CEI EN ISO 15223-1:2013** “Medical Devices – Symbols to be used in medical devices’ label, in labeling and in the information to be provided”

## 2. License plate label

The following indelible adhesive label is applied to the back of the defibrillator:

|                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <b>progetti</b><br>Medical Equipment Solutions<br>www.progettimedical.com                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>DEFIBRILLATOR</b><br><b>REF RESCUE LIFE</b><br><b>SN</b> <input type="text"/><br> <b>PROGETTI S.r.l.</b><br>10028 Trofarello (TO)<br>Strada del Rondello, 5<br><b>MADE IN ITALY</b> | Applied parts: CF  BF <br>Medical device class (MDD 93/42/EEC): <b>II b</b><br>Electrical class (IEC 60601-1): <b>2</b> <br><b>100 - 230 V ~   50 - 60 Hz   700 mA</b><br><b>INTERNAL Li-Ion batteries</b> |
| <b>CE</b> 0068                                                                                                                                                                                                                                                            | <b>CAUTION – HAZARDOUS ELECTRICAL OUTPUT</b><br>This equipment is for use ONLY by qualified personnel<br><b>CAUTION – ELECTRIC SHOCK HAZARD</b><br>Do NOT remove the back cover. Refer servicing to qualified service personnel.<br><b>DANGER</b><br>Possible EXPLOSION hazard if used in presence of concentrated oxygen                                                                                                                                                 |

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### 3. Packaging label

|                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                             |
| <b>DEFIBRILLATOR</b><br><b>REF RESCUE LIFE</b><br><b>SN</b> <input type="text"/><br> <b>PROGETTI S.r.l.</b><br>10028 Trofarello (TO)<br>Strada del Rondello, 5<br>MADE IN ITALY                                                                                                                                                                                            | Language: <input type="text"/><br>SW Version: <input type="text"/><br>Optional: AED <input type="checkbox"/> Pacemaker <input type="checkbox"/> NIBP <input type="checkbox"/> SpO2 <input type="checkbox"/> |
|  0068<br>-20 °C  +70 °C  90%<br>5%   |                                                                                                                                                                                                             |

### 4. Plan of accessories' labels

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |
| RESCUE LIFE Accessory / Accessorio<br><b>ECG Patient Cable/ Cavo Paziente ECG</b> <input type="text" value="5 wires/ 5 fili"/><br><b>REF</b> DFBLIFCAB5                                                                                                                                                                                                                                                                                                                                                                                         |  |
|   -20 °C  +70 °C  90%<br>5%   |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |
| RESCUE LIFE Accessory / Accessorio<br><b>SpO2 Sensor / Sensore SpO2</b> <input type="text"/><br><b>REF</b> <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|   -20 °C  +70 °C  90%<br>5%   |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |
| RESCUE LIFE Accessory / Accessorio<br><b>ECG Patient Cable/ Cavo Paziente ECG</b> <input type="text" value="10 wires/ 10 fili"/><br><b>REF</b> DFBLIFCAB10                                                                                                                                                                                                                                                                                                                                                                                      |  |
|   -20 °C  +70 °C  90%<br>5%   |  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |
| RESCUE LIFE Accessory / Accessorio<br><b>Disposable Electrodes Cable / Cavo Elettrodi Monouso</b><br><b>REF</b> DFBLIFADPT                                                                                                                                                                                                                                                                                                                                                                                                                                |  |
|   -20 °C  +70 °C  90%<br>5%   |  |

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## 5. Description of the symbols used

| SYMBOL                                                                              | MEANING                                                   | POSITION                                                                                                                                                       |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Device's name                                             | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation            |
|    | Device's serial number                                    | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation            |
|    | Manufacturer's identification                             | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation |
|   | Device's manufacturing date                               | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation            |
|  | CF TYPE applied part protected by defibrillator discharge | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|  | BF TYPE applied part protected by defibrillator discharge | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|  | Device electrical class 2                                 | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |

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|-------------------------------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Alternate                                                   | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|    | Electrical hazard                                           | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|    | Warning                                                     | <input checked="" type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|    | DO NOT use AED mode on newborns                             | <input type="checkbox"/> on product<br><input type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation                       |
|   | Read enclosed instructions for use                          | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation |
|  | CE signature and Identification Number of the Notified Body | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation |
|  | Temperature storage range                                   | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |
|  | Humidity storage range                                      | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation            |

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|                                                                                    |                                                        |                                                                                                                                                                |
|------------------------------------------------------------------------------------|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Identification of the number of stackable packages: 4  | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation                       |
|   | Symbol for marking electrical and electronic equipment | <input checked="" type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input checked="" type="checkbox"/> on the documentation |
|   | Fragile content, handle with care                      | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation                       |
|   | Keep upwards                                           | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation                       |
|  | Keep dry and do not expose to weather conditions       | <input type="checkbox"/> on product<br><input checked="" type="checkbox"/> on packaging<br><input type="checkbox"/> on the documentation                       |

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