MEDICAL DEVICE

Name : **FRED EASY G2**
GMDN code : 48047
EMDN code : Z120305 Defibrillators
Basic UDI-DI : 761336590143E5
File N° : CE ARE 0143
Commercial reference or article code:

Part number	UDI-ID (GTIN)	Description
1-143-9901	07613365900644	FRED EASY G2 DA
1-143-9902	07613365900651	FRED EASY G2 DSA
1-143-9903	07613365900668	FRED EASY G2 ONLINE DA
1-143-9904	07613365900675	FRED EASY G2 ONLINE DSA

Intended purpose:
The **FRED EASY G2** is a defibrillator for intra or extra hospital use, intended for cardiac arrest management.
The device allows to:

- deliver defibrillation shocks in automatic, semi-automatic on patients presenting shockable ECG rhythms;
- provide guidance for CPR.

MANUFACTURER

NAME : SCHILLER MEDICAL
Address : 4, rue Louis Pasteur – 67160 Wissembourg – France
Unique registration number: FR-MF-000003190

REGULATIONS / APPLICABLE UNION LEGISLATION

This EU Declaration of Conformity attests that the above medical device complies with:

- **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;
- Directive 2014/53/UE of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

CLASSIFICATION

FRED EASY G2 is a « medical device » defined by the **Regulation (EU) 2017/745** as,

« any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

☒ diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

☐ diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

☐ investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

☐ providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Class of risk : III

Rule : 22

« Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III. »

COMMON SPECIFICATIONS

No reference to common specifications has been used.

NOTIFIED BODY

NUMBER : 0459
Name : GMED
Address : 1, rue Gaston Boissier – 75724 PARIS Cedex 15 – France

Conformity assessment : Annex IX, chapters I, II and III (Quality management system + assessment of the technical documentation)

Certificate N° : 39329 rev.1
Date of validity: June 26, 2023
Valid until : June 25, 2028

ENGAGEMENT

I, the undersigned, Valérie ENGEL, Regulatory affairs manager of the company SCHILLER MEDICAL, 4, rue Louis Pasteur – 67160 Wissembourg, France, certify that:

- this EU Declaration of Conformity is issued under the sole responsibility of SCHILLER MEDICAL according to Annex IV of Regulation (EU) 2017/745 ;
- the medical device designated above meets the General Safety and Performance Requirements of Regulation (EU) 2017/745 (Annex I);
- the medical device designated above meets the Essential Requirements of Directive 2014/53/EU (Article 3);
- the CE marking is affixed in accordance with Annex V of Regulation (EU) 2017/745 and Articles 19 and 20 of Directive 2014/53/EU.

Place : Wissembourg
Date : June 27, 2023
Name : Valérie ENGEL
Function : Regulatory Affairs manager
Signature :

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APPENDIX 1: ASSOCIATED ACCESSORIES

Use with module	Part Number	Description	Legal manufacturer	Manufacturer's Part Number	Risk class acc to Annex VIII MDR or Annex IX MDD
Defi	0-21-0040	1 pair disposable adhesive defibrillation electrode pads for adults,80 cm² pre-connected with RFID	Leonhard Lang GmbH	50812	I
	2.155067	1 pair of disposable adhesive defibrillation pads for children, 42 cm²		50830	I
CPR Feedback	2-62-0003	ARGUS LifePoint 2 feedback sensor	Schiller AG	2.100870	I
	0-08-0000	Securing pads LifePoint feedback sensor (set of 5 pcs)		2.100519	I

APPENDIX 2: ASSOCIATED NON-MEDICAL DEVICES, SPARE PARTS AND COMPONENTS

Use with module	Part Number	Description
Main device	4-07-0042	LiMnO2 Battery pack FRED easy G2
	4-07-0041	Li-Ion Battery pack, rechargeable, FRED easy G2
	1-143-5081	Li-Ion CS-4 charger
	6-17-0026	Angled USB Adapter
	0-80-0041	Carrying Bag (Red)

Tableau de suivi des modifications / Modification history table :

Release	Date	Author	Description
1	27/06/2023	V. ENGEL	*Creation*