Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ECO-27/11-1 din 27.11.2023

Solicitantul Ecochimie SRL, cu sediul Republica Moldova, mun. Chișinău, str. Valea Crucii 2, of. 85, tel./fax: 022109111, e-mail info@ecochimie.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Numărul de catalog (referinţă)*	Denumire generică (denumirea dispozitivului)
1	MCC-E5	Miniaturize Chest Compressor

Se anexează următoarele acte:
1. Autorizație de la producător
2. Certificat CE
3. Certificat ISO13485
4. Lista de bunuri
5. Catalog
6. Declarație pe proprie răspundere

Data 27.11.2023 Semnătura _____

Digitally signed by Iurcu Nicolae
Date: 2023.11.27 12:21:04 EET
Reason: MoldSign Signature
Location: Moldova

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Letter of Authorization

We, **SunLife Science (Suzhou) Inc.,**
based in **211, B2 Building, 218 Xinghu Str., Suzhou industrial Park, China**

assign **ECOCHIMIE SRL**,
based in **Valea Crucii str., 2/85, MD-2062, mun. Chișinău, Republic of Moldova**.

as **authorized representative** in correspondence with the conditions of Council Directive 93/42/EEC

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 from 09.06.2017 regarding medical devices.

This authorization shall apply to the following medical devices:
Miniaturize Chest Compressor
Model number: MCC-E5

This authorization letter is valid until 31/12/2024

Place: **Suzhou**
Date: **27.11.2023**
Signed: _____

SunLife Science(Suzhou), Inc.
211, B2 Building , 218 Xinghu Str., Suzhou Industrial Park, China
Zip code: 215028 Hotline: +86 4001 021 120
E-mail:marketing@sunlifescience.com
www.sunlifescience.com

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
13130-2018-CE-RGC-NA-PS Rev. 1.0	PRJC-565810-2017-PRC-CHN	27 May 2024

This is to certify that the quality system of:

SunLife Science (Suzhou) Inc.

211, B2 Building, 218 Xinghu Str., Suzhou Industrial Park, China

For design, production and final product inspection/testing of:

MINIATURIZE CHEST COMPRESSOR

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 28 May 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Mariann Jeremiassen

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	06-01-2020
1.0	**EU Representative Change**	**2020-05-28**

Products covered by this Certificate:

Product Description	Product Name	Class
Miniaturize Chest Compressor	MCC-E1, MCC-E2, MCC-E3, MCC-E4, MCC-E5	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
SunLife Science (Suzhou) Inc.	211, B2 Building, 218 Xinghu Str., Suzhou Industrial Park, China

EU Representative
WellKang Ltd
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

Certificate No.:	Project No.:	Valid Until:
13130-2018-CE-RGC-NA-PS Rev. 1.0	PRJC-565810-2017-PRC-CHN	27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
13130-2018-CE-RGC-NA-PS Rev. 1.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
SunLife Science (Suzhou) Inc.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A new EU representative, replacing the one stated on the certificate, has been accepted.

EU Representative
WellKang Ltd Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Original Appendix	20 December 2021
1.0	EU Representative Address Change	10 January 2023

Place and date:
Høvik, 10 January 2023

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
246824-2017-AQ-RGC-NA-PS Rev. 2.0

Initial certification date:
08 January 2018

Valid:
27 February 2022 – 26 February 2025

This is to certify that the management system of

SunLife Science (Suzhou) Inc.

211, B2 Building, 218 Xinghu Str., Suzhou Industrial Park, China
(Unicode: 91320594MA1MC1CR4W)

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Development, Manufacturing, Servicing, Marketing, Sales and Distribution of Chest Compressor and Indicator of CPR.

Place and date:
Høvik, 21 January 2022

NORWEGIAN ACCREDITATION

MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	MCC-E5	Miniaturize Chest Compressor	SunLife	**Sistem de compresie toracica**	

Iurcu Nicolae *Semnătura* _____
Director *Data 27 noiembrie 2023*

Miniaturize Chest Compressor MCC-E5

MCC-E5 TECHNICAL SPECIFICATIONS

COMPRESSIONS

COMPRESSION MODE
1)Continuous mode
2)30:2 mode

COMPRESSION DEPTH
Fixed depth is 52 ± 2mm
Setting range is 30 to 55 mm ± 2mm

COMPRESSION DUTY CYCLE
50±5%

COMPRESSION FREQUENCY
Fixed-rate is 102 ± 1 compressions per minute
Setting range is 100 to 120 ± 1 compressions per minute

AC POWER ADAPTER

SIZE(length×width×height)
205mm×105mm×48mm

OUTPUT
DC25.9V

INPUT
100V-240V~，50Hz/60Hz

POWER
200VA-550VA MODEL NUMBER

PHYSICAL

SIZE(length×width×height)
192mm×163mm×175mm

SERVICE LIFE
8 years

WEIGHT(with battery pack)
3.1Kg

PHYSICAL SPECIFICATIONS OF BATTERY

SIZE(length×width×height)
120mm×55mm×150mm

TYPE
Rechargeable Lithium battery

WEIGHT
Less than 600g

MAXIMUM BATTERY CHARGING TIME
Not more than 4hours (25℃)

BATTERY VOLTAGE(NOMINAL)
DC25.9V

BATTERY TEST CYCLE TIME
Each test cycle shall not exceed 10

SPECIFIED REPLACEMENT INTERVAL
300 full charge/ discharge cycles

BATTERY CAPACITY
3000mAh(typical)

INITIAL BATTERY OPERATION TIME (NOMINAL PATIENT)
Continuous working time not less than 60 minutes

CAUTION: The battery may not work after 300 full charge/discharge cycles

MAIN UNIT ENVIRONMENTAL

OPERATING TEMPERATURE
-5℃～+45℃
-20 ℃ to ＋50 ℃ for 1 hour after storage at room

HUMIDITY
5%~93(3)%,non-condensing

STORAGE ENVIRONMENT
-40℃～+70℃
The maximum time required for the MCC-E device to adapt to operating temperature after storage is 2 hours.

OPERATING ATMOSPHERIC PRESSURE
62kPa ~ 106kPa

DEVICE IP CLASSIFICATION(IEC60529):
IP34

BLUETOOTH WIRELESS RANGE
2400MHz-2483.5MHz

BLUETOOTH RECEIVER SENSITIVITY
Maximum-96dBm

BLUETOOTH TRANSMIT POWER
≤20dBm （EIRP）

POWER REQUIREMENT
DC25.9V

BATTERY ENVIRONMENTAL PARAMETERS

STORAGE ENVIRONMENT
0℃ ~ 45℃, dry environment (recommended temperature is 20℃, humidity below 50%). (At -20℃ ~ 0℃ and 45℃ ~ 60℃, should not be stored for more than1month)

CHARGING TEMPERATURE
0℃ ~ 45℃

DISCHARGING TEMPERATURE
-20℃ ~ 60℃

ELECTRONIC CONTROL UNIT

INPUT VOLTAGE
5V

WiFi FREQUENCY RANGE
2400MHz-2483.5MHz

SCREEN RESOLUTION
256×64

WiFi TRANSMIT POWER
13dBm

WiFi WIRELESS STANDARD
802.11b/g/n

WiFi RECEIVER SENSITIVITY
-82dBm

SunLife Science(Suzhou), Inc.

211, B2 Building , 218 Xinghu Str., Suzhou Industrial Park, China
Zip code: 215028 Hotline: +86 4001 021 120
E-mail: marketing@sunlifescience.com
www.sunlifescience.com

Performing CPR without measuring the effects is like flying an airplane without an altimeter.

----Dr. Max Harry Weil , 4th WolfCreek, April 1996

Our Mission of Saving Lives Enlightens the Power of Innovation

1.0 2.0 3.0

Resuscitation 1.0

Age of Manual Chest Compression

In 1891 Dr. Friedrich Maass first performed external chest compression on people. Dr. William Kouwen-hoven, Dr. Guy Knickerbocker, James Jude and others have developed external chest compression technology. In 1960, JAMA published the research results of 20 hospital cardiac arrest cases, and 14 of these 20 patients were discharged from the hospital. The authors wrote: "Now, anyone, at any time, can learn rescue measures", AHA officially approved cardio-pulmonary resuscitation in 1963 and issued the first CPR standard in 1963.

Resuscitation 2.0

Age of Mechanical Chest Compression

In 1964, the earliest CPR machine "Thumper" was introduced. It simulated manual chest compression to reduce the fatigue of people and gradually became an important supplement to manual compression. Subsequently, the three generations of mechanical CPR equipment based on the cardiac pump theory, thoracic pump theory and cardiothoracic pump combination were introduced one after another. Typical representatives are Lucas of Physio-Control, Autopulse of ZOLL and Weil MCC of SunLife.

Resuscitation 3.0

Age of Intelligent and Accurate Resuscitation

In 2013, the Journal of Circulation published AHA expert consensus, which was a milestone for the quality of CPR, namely "CPR Quality: Improving Cardiac Resuscitation Outcomes Both Inside and Outside the Hospital". It pointed out the "3 + 5" factors affecting high-quality CPR. The AHA & ERC Guidelines in 2015 emphasized the importance of immediate high-quality CPR, feedback on CPR, registration of resuscitation data, and continuous quality improvement. Navigated by 3.0 compression technology, Resuscitation 3.0 implements personalized compression strategies according to the unique demands of different patients which continuously develops intelligent, personalized and closed-loop resuscitation.

SunLife®
Save More Lives

SunLife Science(Suzhou) Inc.
211, B2 Building , 218 Xinghu Str.,
Suzhou Industrial Park, China
marketing@sunlifescience.com
Hotline: +86 4001 021 120

Website

Sunlife Medical
Sunlife Science
Sunlife Medical
Sunlife Medical

www.sunlifescience.com

MCC-E

Electric-driven 3D Chest Compressor

Technology from Weil Institute

Resuscitation Warrior, Leading Resuscitation 3.0

SunLife
Save More Lives

MCC-E

Electric-powered 3D Chest Compressor

Product Description: Miniaturize Chest Compressor
Product Name: MCC-E1, MCC-E5

*AHA & ERC Guidelines emphasize that rescuers should reduce the number and time of interruption of chest compressions as much as possible, and increase of chest compression fraction (CCF)， with the target proportion of at least 60%. MCC-E is suitable for use in various complex environments such as first aid sites, stairway,and ambulances, reducing interruptions and achieving accurate CPR.

* The AHA Guidelines recommend to use mechanical CPR device in 7 scenarios: limited number of rescuers, prolonged CPR, CPR during mild hypothermia, CPR in moving ambulance, CPR in angiography room, and CPR in the environment with high risk of cross-contamination. MCC-E fully complies with the AHA Guidelines and provides high-quality chest compression.

Low Compression Risk

- Soft start, provide the adaptation period to compression, reduce the risk of fracture.
- 3D compression combines the theory of cardiac pump and thoracic pump, reducing the impact of compression.
- Low gravity center (<15cm), avoid toppling and hurting patients when moving at a high speed.
- Battery can work for 60 minutes and the device can work while charging, which make the compression uninterrupted.

Improve Resuscitation Efficiency

- 3D compression, patented by Weil Critical Care Medicine, provides higher CPP.
- Keep continuous high-quality compression in mobile environment and stairway transportation to maximize CCF.
- Thoracic cavity is three-dimensional fixed, which makes the compression position consistent without displacement.

Suitable for Complex Environment

- IP34 and EN1789 Certification.
- Support the work at 45° inclination for Head-Up CPR.
- Applicable to the preparation of ECPR, hypothermia treatment, and PCI treatment.
- Separating of compression & operation by using the smart control panel

Smart Tool for Resuscitation

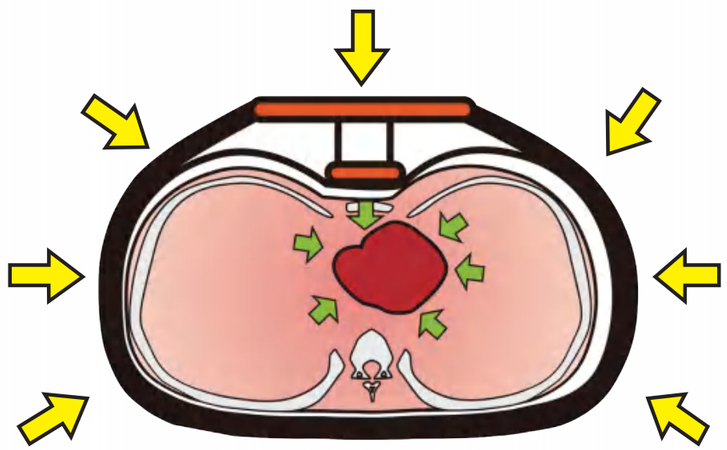
- Adjustable compression depth & rate, help users to develop the optimal compression strategy for different patients.
- CPR data can be displayed in real time and CCF value is available after each compression.
- Multiple data communication options, including USB, Bluetooth and WiFi.
- An ideal tool to help build a Continuous Quality Improving system for monitoring, analysis and improvement

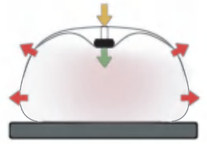
Weil 3D Compression Technology

External Pressure

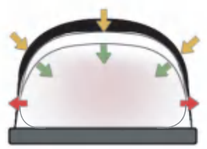
Internal Pressure

Lateral Released Pressure

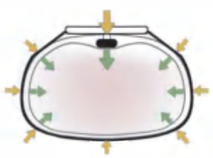




1st Generation



2nd Generation



3rd Generation

* 3D compression technology combines the advantages of cardiac pump theory and thoracic pump theory, and is the third generation of CPR technology. Currently the technology has been used in over 2000 clinical institutions.

High Efficiency and Less Injuries

Experiment Items	1st Generation	3rd Generation	Explanation
Comparison of Coronary Perfusion Pressure (CPP) and required chest compression depth	12-20 mmHg 5.3 - 6.1 cm	14-50 mmHg 3.0 - 3.5 cm	50% compression depth delivered by Weil MCC has the same effect as 100% compression depth delivered by other brand
Intrathoracic Positive Pressure	10 mmHg	31 mmHg	Facilitates blood circulation
Intrathoracic Negative Pressure	- 3 mmHg	- 10 mmHg	Better for blood perfusion
Number of Broken Ribs	Average 2.75	Nil	Less to none complication and injury
48 hours after ROSC on Neurobehavioral Assessment Scale(NAS)	47.5	97.5	Better neuro recovery
Carotid Blood Flow (CBF)	23.5mL/min	42.3mL/min	Better cerebral blood

Data source: Wei Chen, MD ,PhD; Yinlun Weng, PhD; Xiaobo Wu, BME; Shijie Sun, MD, FCCM; Joe Bisera,MSEE; Max Harry Weil, MD, PhD, MCCM; Wanchun Tang, MD, MCCM. The effects of a newly developed miniaturized mechanical compressor on outcomes of cardiopulmonary resuscitation in a porcine model, Crit. Care Med 2012 Vol 40 No. 11:3007-3012

* Coronary Perfusion Pressure (CPP) is a key index to measure the resuscitation quality. The research paper published in the American Journal of Critical Care Medicine shows that compared with general mechanical CPR device, the experimental group using Weil 3D compression technology can achieve a better perfusion effect with half of the compression depth. Weil 3D compression technique is the method closest to open chest compression in non-invasive state.

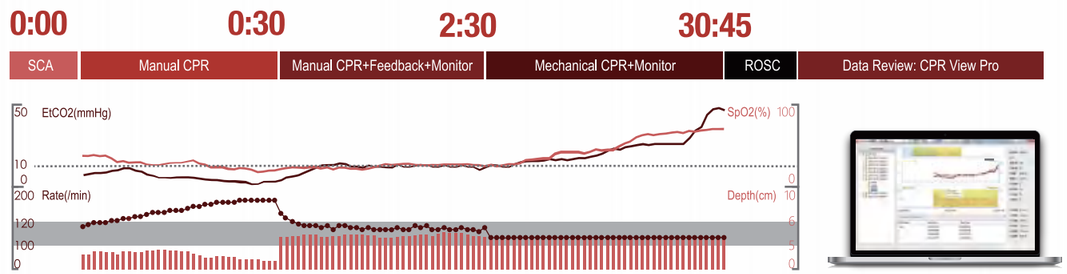
Smart Control Panel
Making Resuscitation Visible and Fully Controllable

*AHA guidelines and AHA experts agree on the research direction of improving the quality of CPR in the future: further clarify the relationship between CPR characteristics, determine the best CPR characteristic indicators (CCF, rate, depth, etc.), and their relative importance to the patient outcome.

- Visible data, with 2.8 inches OLED screen feeding back the compression data in real-time.
- The depth and rate of compression can be adjusted for personalized treatment and scientific research.
- Statistics of CCF and other resuscitation data can be generated immediately after the rescue is completed.
- Large data capacity with the capacity of 180 hours of data.
- Supporting multi-channel transmission including USB, WiFi, and Bluetooth.
- CPR data cloud provides access to regional cardiac arrest events registration.

Continuously Accurate CPR

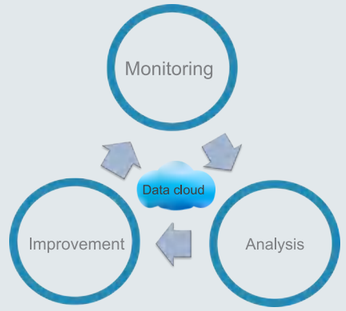
Continuously Accurate CPR (CA CPR) is a resuscitation system composed of continuous high-quality CPR, including immediate high-quality compression, resuscitation cycle monitoring, and full data review.



*MCC- is equipped with a 2.8 inches OLED display screen to show CPR data in real-time. The entire resuscitation data is automatically stored. A report can be generated for retrospective analysis, which makes it a scientific assistant for clinical quality control, scientific research and regional CPR data registration.

- Display Parameters:
  Compression rate, compression depth, compression mode, rescue time, event number, battery status and wireless connection.
- Adjustable Parameters:
  Compression rate, compression depth, compression mode, date and time, data transmission mode and language.
- Statistical Data:
  CCF, compression rate, compression depth, rescue time, compression time and interruption time.

- Resuscitation cycle: MCC-E can carry out wireless data linkage with a monitor system to establish and implement a resuscitation feedback mechanism. It means compression parameters and patient physiological parameters can be monitored on the same screen, which allows medical professionals to observe the patient's resuscitation progress in the whole process.
- Res Full review of resuscitation data: The resuscitation data on MCC-E is automatically stored. It can be exported to CPR View Pro software to review and analyze compression and patient physiological parameters. It is useful in clinical quality control, scientific research and regional CPR data registration.
- CPR View Pro and CPR data cloud platform provide the basic information that aims at the improvement of each element of the training and rescue process



Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: ECOCHIMIE SRL, cu sediul Republica Moldova, mun. Chișinău, str. Valea Crucii 2, of. 85,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)
1	MCC-E5	Miniaturize Chest Compressor

Se anexează următoarele acte:
1. Autorizație de la producător
2. Certificat CE
3. Certificat ISO13485
4. Lista de bunuri
5. Catalog

Sunt autentice și corespund realității.

Iurcu Nicolae *Semnătura* _____
Director *Data 27 noiembrie 2023*