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.

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.sunlifescien

Digitally signed by Iurcu Nicolae
Date: 2023.11.27 12:21:07 EET
Reason: MoldSign Signature
Location: Moldova

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

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