Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: FZ 7673-2019

Date: 26/04/2019

Order No.: AP6421-2018

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

GIÁM ĐỐC
M.S.D.N: 0316574096 CÔNG TY TNHH TRANG THIẾT BỊ Y TẾ IMD
Trần Quang Nguyên

NAME: LIFE INSTRUMENT CORPORATION

ADDRESS: 91 FRENCH AVENUE BRAINTREE, MA 02184 USA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 12/03/2019 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (288 PAGES, 15 DEVICES)

As of the 13/03/2019, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on these devices;

- May place these devices in the European EU and EEA territory,

G. ELKAYAM C.E.O
Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. : 32 2 732 59 54 Fax : 32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa

EAR

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*also applicable to Class I s & m
**This certificate will become void automatically if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

CE