

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: FZ 7673-2019

Order No.: AP6421-2018

Date: 26/04/2019

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:



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.

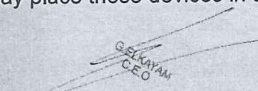
The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here below, are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


Obelis s.a. - O.E.A.R.C.
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1030 Brussels
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Mr. G. Elkayam CEO
Obelis sa



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.

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