Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF MDD NOTIFICATION

Ref. No.: FZ 8809-2020

Date: 13/03/2020

Order No.: FZ 8756-2020

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: I3 BIOMEDICAL INC.

ADDRESS: 14163 BOUL DU CURE LABELLE, SUITE 50 MIRABEL, QC J7J1M3 CANADA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * device complies 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 11 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical device, as stipulated here below, is fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 12/03/2020 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICE: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 13/03/2020, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on this device;

- May place this device in the European Union and EEA territory.

G. ELKAYAM C.E.O.

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

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 Is and Im

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

CE

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Annex A - List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	TAS-100	TrioMed Active Surgical and Medical Mask	surgical facemask	single use, surgical facemask	35177	I	1

Devices already circulating on the EU market ⚠ ☐ Yes ☑ No

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

Obelis s.a.

Signature: G. ELKAYAM C.E.O.

Stamp:

Obelis s.a. - O.E.A.R.C.
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