CERTIFICATE OF MDD NOTIFICATION

Ref. No.: GB 1570-2021

Date: 01/06/2021

Order No.: GR 0792-2021

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: BISTOS CO., LTD.

address: 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

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 11 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 20/05/2021 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

Class I medical devices: please see Annex A - List of Devices (1 Page, 11 devices)

As of the 01/06/2021, 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 Union and EEA territory.

Digitally signed by Potînga Stela
Date: 2025.07.29 16:18:58 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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.

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V3 – ID: 00454516 – 22/02/2019

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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 / GIVD Code	Class	Rule (only for MDD)
1.	model no.: BT-410A, BT-410F	EYESCOPE	Head-worn Lamp; Medial examination light	Using for the medical examination or therapeutic procedure by fixing it on the head and illuminating with condensed light to get a clear sight of the injured part.	46807	I	12
2.		Single Pump kit	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
3.		Dual Pump kit	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
4.		Funnel	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
5.		Diaphragm Set	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
6.		Air tube Set	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
7.		Funnel Block	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
8.		Funnel Cap	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
9.		Bottle Set	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
10		Nipple	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1
11		Diaphragm	Breast pump support kit reusable.	It is used in conjunction with electric breast pump to assist in exctracting for collection and/or feeding.	61734	I	1

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)

G. ELKAYAM C.E.O

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