

CERTIFICATE

OF

MDR NOTIFICATION

Ref. No.: CMB 1579-2021

Date: 01/06/2021

Order No.: CMB 8827-2020

This is to certify that, according to the Regulation (EU) 2017/745 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: Shaoxing Yibon Medical CO., Ltd

address: No. 341, Yuewang Road, Paojiang Industrial Zone Shaoxing 312000 Zhejiang, China

as stipulated and demanded by the aforementioned regulation

The Manufacturer declares that the Class I * devices comply with the Regulation including all general safety and performance requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Regulation (EU) 2017/745 article 52 requirements, including the EC Declaration of Conformity (according to Annex IV) confirming that their Class I medical devices, as stipulated here below, are fulfilling the applicable requirements of the Regulation (EU) 2017/745.

The notification of the following medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 26/05/2021 in compliance with the Regulation (EU) 2017/745.

Class I medical device(s): please see Annex A - List of Devices (2 Pages, 21 devices)

As of the 27/05/2021, 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,



Obelis s.a. - O.E.A.R.C.
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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 Is, Im and Ir

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

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V3 - ID: 00454516 - 22/02/2019

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



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Annex A - List of Devices

(REGULATION (EU) 2017/745 on medical devices)

#	Catalogue reference number	Commercial Name	Short description and intended use	Device already on the EU market? (y/n)	Legacy device - ART 120 - to be placed on the market after 26/05/21? (y/n)	GMDN Code	BASIC UDI - DI	Class and Rule	
1.	YB/CE-33	Gauze swabs/balls/rolls	Absorb blood, exudation fluid, and clean wound in clinical care operation	y	n	48130	6972370761200000LP	I	4
2.	YB/CE-34	Non-woven swabs/balls/pads	Absorb blood, exudation fluid, and clean wound in clinical care operation	y	n	48130	6972370762200000M8	I	4
3.	YB/CE-35	Cotton balls/rolls/pads	Combine with disinfectant for cleaning skin and small wounds	y	n	63281	6972370761000000KV	I	4
4.	YB/CE-36	Crepe/elastic/gauze bandage	Support a medical dressing, in its own to provide support to the body	y	n	10284	6972370763000000LX	I	1
5.	YB/CE-37	Absorbent pad	Absorb blood, exudation fluid, and clean wound in clinical care operation	n	n	48133	6972370766900000S7	I	4
6.	YB/CE-38	Cotton tipped applicator	Combine with disinfectant for cleaning skin and small wounds	y	n	47077	6972370764600000PW	I	4
7.	YB/CE-39	Alcohol swabs	To be used before injections or care operation for disinfecting intact skin	y	n	13913	6972370764800000QQ	I	1
8.	YB/CE-40	Face masks	Intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.	y	n	35177	6972370764100000MV	I	1
9.	YB/CE-41	Kocher / plastic Forceps	For clip medical dressings.	y	n	11791	6972370769010000QG	I	1
10.	YB/CE-42	Cups	Medical container or receiver, for washing or holding liquid, instruments, dressing etc.	n	n	12505	6972370769010050QX	I	1
11.	YB/CE-42	Bowls	Medical container or receiver, for washing or holding liquid, instruments, dressing etc.	n	n	42891	6972370769010080R8	I	1
12.	YB/CE-42	Trays	Medical container or receiver, for washing or holding liquid, instruments, dressing etc.	y	n	42891	6972370769020000QT	I	1

13.	YB/CE-43	Paper pulp Tray	A tray designed to hold supplies and provide a platform for organizing, preparing, and administering medication. It can hold items, e.g. medication cups, syringes, medication cards, alcohol swabs, needle destruction devices and disposal bags.	y	n	42891	6972370769020050RA	I	1
14.	YB/CE-44	Nurse caps	Suitable for use by nurses in basic care operation as general isolation	y	n	32297	6972370764400000P4	I	1
15.	YB/CE-45	Dental bib	For dental oral examination, put it on your chest to avoid contamination of oral fluids	y	n	61050	6972370764760000SD	I	1
16.	YB/CE-46	Tongue depressor	Lowering the tongue during oral examination	y	n	14066	6972370765100000NE	I	5
17.	YB/CE-47	Foil blankets	Reduce shock, keep patient warm, dry and clean helps against hypothermia	n	n	10416	6972370765710000R7	I	1
18.	YB/CE-48	Injection plaster	Used for fixing injection needles tubes and dressing.	y	n	16886	6972370766010000NV	I	1
19.	YB/CE-49	Adhesive dressing roll/tape	For fixing medical dressing.	y	n	16886	6972370766020000P8	I	1
20.	YB/CE-50	Isolation gown	A multipurpose garment worn by healthcare providers or visitors to isolate them from the patient. The isolation gown protects the patient, or it can protect the healthcare provider or visitor from a contagious agent which has infected the patient. This is a disposable garment.	y	n	35492	6972370764300000NP	I	1
21.	YB/CE-51	Medical shoe cover	This is a device that is CPE/ non woven and non skid that is intended to be used to act as a physical barrier on a shoe to prevent cross-contamination between the shoe and the environment.	y	n	15056	6972370764500000PH	I	1

* Annex A is part of the Agreement.

** The above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Annex VII - REGULATION (EU) 2017/745)

dt
dt (Jun 3, 2021 18:16 GMT+2)

G. ELKAYAM
C.E.O.

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

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