CERTIFICATE OF MDR NOTIFICATION

Ref. No.: TP 1164-2021

Date: 06/04/2021

Order No.: PV 9050-2020

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: MICRO BVM SYSTEMS, LTD.

ADDRESS: RUZIN STREET, 11, JERUSALEM, 93870, ISRAEL

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 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 01/03/2021 in compliance with the Regulation (EU) 2017/745.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (3 PAGES, 4 DEVICES)

As of the 02/03/2021, 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,

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld General Wahis 53
1030 Bruxelles

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.

* 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	GMDN Code	BASIC UDI - DI	Risk class	Classific. Rule
1.	PBVM G (003XP)	Pocket BVM™ Manual Resuscitator with O2 tubing	The Pocket BVM is a manual emergency ventilator device whose purpose is to manually apply positive pressure to a patient's airways to support ventilation and oxygenation, The Pocket BVM incorporates bags and valve assemblies and is intended to provide emergency respiratory support to a patient through a face mask or a tube Inserted into the patient's airway	36086	729001682400BB	I	2

2.	PBVM C (002)	Pocket BVM™ Manual Resuscitator	The Pocket BVM is a manual emergency ventilator device whose purpose is to manually apply positive pressure to a patient's airways to support ventilation and oxygenation, The Pocket BVM incorporates bags and valve assemblies and is intended to provide emergency respiratory support to a patient through a face mask or a tube Inserted into the patient's airway.	36086	729001682400BB	I	2
3.	PBVM TAC	Pocket BVM™ Manual Resuscitator Tactical	The Pocket BVM is a manual emergency ventilator device whose purpose is to manually apply positive pressure to a patient's airways to support ventilation and oxygenation, The Pocket BVM incorporates bags and valve assemblies and is intended to provide emergency respiratory support to a patient through a face mask or a tube Inserted into the patient's airway.	36086	729001682400BB	I	2

4.	MBVM EXT	Pocket BVM™ Extension tube	The Pocket BVM is a tube to connect to manual emergency ventilator device whose purpose is to manually apply positive pressure to a patient's airways to support ventilation and oxygenation, The Pocket BVM incorporates bags and valve assemblies and is intended to provide emergency respiratory support to a patient through a face mask or a tube Inserted into the patient's airway.	36086	729001682486CF	I	2

* 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 (Annex VII - REGULATION (EU) 2017/745)

Obelis s.a.

Signature:

Stamp

G.ELKAYAM C.E.O.

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