

# E.A.R.-CERTIFICATE

(ARTICLE 11 OF THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES)

REF. NO.: TP 1165-2021

ORDER NO.: PV 9050-2020

DATE: 06/04/2021

**MANUFACTURER:** Micro BVM Systems, Ltd.  
Ruzin Street, 11, Jerusalem, 93870,  
Israel

**FACILITIES:** Micro BVM Systems, Ltd.  
Ruzin Street, 11, Jerusalem,  
93870, Israel

**PRODUCT CATEGORIES:** Please See Annex A - List of Devices (4 Devices, 3 Pages)

**MODELS:** Please See Annex A - List of Devices (4 Devices, 3 Pages)

The European Authorized Representative Center Obelis s.a. declares it will assume the role of European Authorised Representative of the aforementioned manufacturer, provided that the manufacturer complied with the terms and conditions set out in the EAR Services Agreement, which entered into force on 01/12/2019, and the Mandate is signed by both parties in accordance with article 11.2 of the MDR (EU) 2017/745.



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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.

\*This certificate is not a confirmation of product notification nor an approval to place products on the market.

\*\*This certificate will become void automatically upon termination of the EAR agreement or rejection of the products from Obelis PRRC

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



## ANNEX to MDR EAR Certificate

Order No.: PV 9050-2020  
Reference No.: TP 1165-2021

**Manufacturer: Micro BVM Systems LTD**

**Country: Israel**

#	GMDN/ EMDN	Generic device name (including BASIC UDI)	Commercial Name of device	Intended use	Class	Rule	Legacy (Y/N)	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	36086	729001682400BB – Pulmonary resuscitator, manual	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.	I	2	No	Yes	01/02/2021	Yes

2	36086	729001682400BB – Pulmonary resuscitator, manual	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.	1	2	No	Yes	01/02/2021	Yes
3	36086	729001682400BB – Pulmonary resuscitator, manual	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	1	2	No	Yes	01/02/2021	Yes

				a face mask or a tube Inserted into the patient's airway.						
4	36086	729001682486CF – Pulmonary resuscitator, manual	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.	1	2	No	Yes	01/02/2021	Yes

**Date**

**CEO Of Obelis**

**Gideon Elkayam**

  
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