



**MICRO BVM SYSTEMS LTD.**

## **EC DECLARATION OF CONFORMITY**

**Manufacturers Name and Address:** *Micro BVM Systems LTD*

*11 Ruzin Street  
Jerusalem,  
Israel  
POB - 93870*

**Authorized Representative Name  
and Address (if applicable):**

Obelis s.a.  
Bd. Général Wahis 53  
B-1030 Brussels, Belgium  
Phone: 32.2.732.59.54  
Fax: 32.2.732.60.03  
E-mail: [mail@obelis.net](mailto:mail@obelis.net)

We, Micro BVM Systems LTD hereby declare under our sole responsibility that the product(s) listed in Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745. The devices are Class I following Rule 2 of Annex VIII of the REGULATION (EU) 2017/745.

The following conformity assessment procedure has been performed according to article 52 and article 19.

This declaration is also supported by the Quality System Certification EN ISO 13485:2016, issued by IQC- Institute of Quality & Control Ltd, Address 6 Ravnitzky St. Petah Tikva 4900617, Israel, for manufacture and final inspection of the products concerned.

The present declaration is in conformity with Regulation (EU) 2017/745

Micha Oestereich,

### **List of Devices Covered by the Declaration of Conformity**

DoC MDR – ID # 00060320 – V2 – Oct /2020

Page 1 of 3



Phone +972-2-6517191

E-mail [info@microbvm.com](mailto:info@microbvm.com)

Web site <http://www.microbvm.com>

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Class rule applied	BASIC UDI - DI	GMD N/CN D code
1	Pocket BVM™ Manual Resuscitator with O2 tubing	PBVM-G / PBVM003X P -Pocket BVM™ Manual Resuscitator,	The Pocket BVM Resuscitator intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.	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	<b>72900168 2400BB</b>	36086
2	Pocket BVM™ Manual Resuscitator	PBVM-C / PBVM002- Pocket BVM™ Manual Resuscitator,	The Pocket BVM Resuscitator intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.	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	<b>72900168 2400BB</b>	36086
3	Pocket BVM™ Manual	PBVM-T / PBVM002 TAC -	The Pocket BVM Resuscitator	The Pocket BVM is a manual emergency ventilator device whose purpose is to manually	I	2	<b>72900168 2400BB</b>	36086

	Resuscitator Tactical	Pocket BVM™ Manual Resuscitator,	intended for manual pulmonary resuscitation and emergency respiratory support of adult patients.	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.				
4	Pocket BVM™ Extension tube	PBVM-EXT -Pocket BVM™ Extension tube	The Pocket BVM Extension tube intended for support manual pulmonary resuscitation and emergency respiratory support of adult patients.	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	<b>72900168 2486CF</b>	36086

Issue place and date 02/10/2020

*Rotem Arad , CEO*

מיקרו ב.ו.מ. סיסטמס בע"מ  
MICRO B.V.M. SYSTEMS LTD.  
ח.פ. 513851154

