Medicvent AB
Pendelgatan 3
SE-904 22 Umeå
Sweden

Rev 2: February 2020
FSN Ref: 2022-14-1 FSCA Ref: 2022-14

Date: 2022-12-19

Field Safety Notice
Device Commercial Name

For Attention of*:Healthcare professionals in Switzerland that uses the Double Mask to administer medical gases to patients for sedation and short-term pain relief during medical procedures.

Contact details of local representative (name, e-mail, telephone, address etc.)*
LogicAir Sàrl Fin-de-praz 8 2024 St-Aubin SCHWEIZ Ansprechpartner: Mr. Guillaume Kobrin Telefon: +41 32 835 50 89 Telefax: +41 32 835 50 86 E-mail: guillaume.kobrin@logicair.ch Website: www.logicair.ch

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Field Safety Notice (FSN)
Double Mask size 2
The nonconformity does not affect fit, form or function of the device, therefore the risk that the device will harm any patient directly or indirectly is considered low.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The Double Mask is a class lla medical device. It is a reusable anaesthetic face mask that combines two masks in one, a soft inner silicone mask that administer medical gases into the patient; and an outer polysulfone mask that allows to capture leaked gases from the mask for further evacuation. The Double Mask is not distributed as a sterile device. 
1.	2. Commercial name(s)*
	Double Mask, size 2
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Primary purpose of the device is to administer and evacuate general anaesthetic (e.g. Desflourane, Isoflourane, Sevoflourane) and analgesic gases (e.g. Nitrous Oxide, Entonox etc) in childbirth and other pain relief situations.
1.	5. Device Model/Catalogue/part number(s)*
	210002 Double Mask, size 2
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot 3007 / Batch 6670
1.	8. Associated devices
	N/A

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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	It has been identified that the manufacturer has placed 4 pieces of article 210002 Double mask size 2 with lot 3007 and batch 6670 on the swiss market 16 august 2022 without a designated authorised representative in accordance with 812.213 Medical Devices Ordinance of 1 July 2020 (MedDO) art. 104a.
2.	2. Hazard giving rise to the FSCA*
	If any event would occur with the Double Mask there is no designated authorised representative to contact and report to in Switzerland.
2.	3. Probability of problem arising
	The double mask is a low-risk product and has been on the market for 35 years without any adverse events. Complaint rate for the Double Mask in all sizes is 0,28 % on all markets. Complaint rate specific for article 210002 Double mask size 2 is 0 % on all markets for the last two years. The probability that an event will occur is considered low.
2.	4. Predicted risk to patient/users
	The nonconformity does not affect fit, form or function of the device, therefore it is considered to be low risk that the device will harm any patient directly or indirectly.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The issue was identified during yearly ISO 13485/MDD NB Audit.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User*	
	☒ Identify Device ☐ Quarantine Device ☒ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None The four pieces of Double Mask shall be identified and returned to the local representative or destroyed. If the Double Masks are destroyed this must be immediately communicated to the local representative.	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety. As soon as possible, but not later than 12 January 2023

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3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No The nonconformity does not affect fit, form or function of the device, therefore patient follow-up is not required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None The internal process for monitoring regulatory changes on different markets shall be reviewed and updated as needed.	
3.	6. By when should the action be completed?	N/A
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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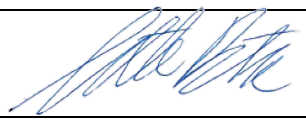
4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Medicvent AB
	b. Address	Pendelgatan 3; SE-904 22 Umeå; SWEDEN
	c. Website address	www.medicvent.se
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Swissmedic has been informed about this communication.	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Linda Bäck QA/RA Manager 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.