Rev 1: September 2018
FSN Ref: 034-2020 FSCA Ref: 034-2020

Date: 15.06.2020

Urgent Field Safety Notice
CO ²-Messleitung 90 cm ((2726) 851/09010)

Contact details of local representative (name, e-mail, telephone, address etc.)*

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Urgent Field Safety Notice (FSN)
CO ²-Messleitung 90 cm ((2726) 851/09010)

Spital Männedorf / Spital Oberwallis

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	CO ²-Messleitung 90 cm ((2726) 851/09010) LOT 120129 in unsteriler Ausführung
1.	2. Commercial name(s)
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Die CO2 Messleitung ist ein Zubehör für Narkose- / Beatmungsgeräte und wird als Verbindung zwischen dem Narkosesystem und dem CO2 Messmonitor eingesetzt. Das Produkt dient zur Probeentnahme von Atemluft ,um den CO2 Gehalt in der Atemluft mittels eines CO2 Messmonitors zu bestimmen.
1.	5. Device Model/Catalogue/part number(s)*
	1851/09010 (2726)
1.	6. Software version
1.	7. Affected serial or lot number range
	120129
1.	8. Associated devices

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	Es ist nicht auszuschließen, dass die CO²-Messleitung nicht durchgängig ist.
2.	2. Hazard giving rise to the FSCA*
	Eine korrekte Kapnagraphie-Messung ist für eine Beatmung essentiell. Die betroffenen Produkte wurden bereits gesperrt oder bereits von der Fa. MK-Med zurückgenommen.
2.	3. Probability of problem arising
	Das Problem ist bisher bei zwei von 1000 produzierten CO²-Messleitungen aufgetreten.
2.	4. Predicted risk to patient/users
2.	5. Further information to help characterise the problem
2.	6. Background on Issue
2.	7. Other information relevant to FSCA

	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	
3.	2. By when should the action be completed?	KW 26-2020
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended?	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None	
3	6. By when should the action be completed?	KW 26 - 2020
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?	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	**3.** For Updated FSN, key new information as follows:	
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:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**SEM-Plastomed GmbH**
	b. Address	**Schulstraße 6 / D-57612 Obererbach**
	c. Website address	**www.plastomed.de**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	**Marco Gehlhausen / QMB**
		

	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.