

Urgent Field Safety Notice

Product Recall

Concerning CODAN Infusion Sets

CODAN Guard® V86-R	REF 43.3905
V86-R	REF 43.4240
V86	REF 43.4270
V86-R	REF 43.4333
V86	REF 43.4435

Lensahn, 25 October 2018

Product Recall V86 – 2018

Sender: CODAN Medizinische Geräte GmbH & Co KG
Stig-Husted-Andersen Straße 11
23738 Lensahn
Germany

Recipient: All CODAN Sales Companies, industrial customers, hospitals concerned

Dear customers,

We ask you to carefully read the following Urgent Field Safety Notice about a necessary product recall and take all actions as described below.



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Identification of the affected medical products:

This product recall refers to the following product lots:

Product Description	Product REF	Lot Number
CODAN Guard® V86-R	43.3905	L72947-1
V86-R	43.4240	E24473-1
V86	43.4270	M87614-1
		E24432-1
		E24433-1
V86-R	43.4333	E24481-1
		E24481-2
		E24481-3
		E24482-1
		E24483-1
		E24483-2
		E24484-1
		M84890-1
		M84891-1
		M84891-2
V86	43.4435	M87088-1

Description of the problem including established root cause:

During the in-process control damaged air filters inside the drip chambers were found. This defect may cause non-sterile ventilation of the product while in use. Further investigations showed that defective drip chambers were used in the products lots detailed above. No other lots are affected by the defect. For the time being we have not received any information about incidents in conjunction with this problem.

Risks:

Contamination of the I.V. solution and consequently infection of the patient due to non-sterile ventilation during I.V. administration cannot be excluded.



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What actions need to be taken by the recipient?

All products of the above mentioned lots that are on hand are to be quarantined to prevent access and use of the sets. Your local CODAN Sales Company will contact you for product return.

Communication of information

Please ensure that this Urgent Field Safety Notice is communicated to all users of the products stated above and other involved persons in your organisation. If you have forwarded any of these lots to third parties, please provide them with a copy of this letter or inform your contact person as stated below.

Please retain this information at least until the measures are completed. The German "Bundesinstitut für Arzneimittel und Medizinprodukte" and all relevant national authorities will receive a copy of this Urgent Field Safety Notice.

Contact persons:

If you have any questions please contact the following contact persons:

For hospitals:

local CODAN Sales Company

For CODAN Sales Companies and industrial customers :

CODAN Medizinische Geräte GmbH & Co KG
Customer Service
Katrin Kassner
Tel.: +49 (0) 4363 – 511 289
Email: kk@codan.de

The CODAN Companies work continuously on the improvement of the product safety to the benefit of or patients and users in order to meet the highest quality and safety standards. We sincerely regret any inconvenience caused. Your assistance in this matter is very much appreciated.

Best regards


Plant Manager


Quality Manager

Encl.

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What needs to be done?

Please ensure that all affected products are immediately identified and quarantined to prevent them from being used. The article (REF) and lot number can be found on each individual package and each packaging unit.

Please complete the customer reply form and return it immediately to:

Name of company:	
Name:	
Tel.:	
Email:	
Fax No.	

We will contact you soonest possible.

Best regards

Signature: _____

Name: _____

Position: _____

Customer Reply Form

Please return this form even if you do not have any of the affected products on stock.

We do not have any of the defective products on stock anymore.

We still have the following quantities of the affected products on stock.

Article number (REF)	Lot Number	Quantity

The products shall be collected from the following address. You will receive a credit note immediately.

Please do not return any products to us without being requested to do so.

Name of the institution:			
Department from which the products are to be collected, if applicable:			
Name of contact person: (please use block letters)			
Address:		Tel.:	
Postcode:		Fax:	
City:		E-Mail:	
Country:			

Date: _____

Name, Position,
Signature: _____