



Recall

- **Oxygen catheter; REF and LOT: see table below**

Dear customer,

We are writing to inform you of our voluntary recall of the following products from ASSAmed GmbH:

Article description	REF	Lot
Oxygen catheter CH10 with step connector and compress	SKKS.10	226.808; 255.809; 334.811; 344.812

We have received information from the market that certain catheters from the aforementioned lot do not allow clear passage of air.

Once we noticed this error, we voluntarily decided to recall products from the lot in question to avoid any risk to patients, users and third parties.

Recipient

Users and distributors

Problem

Random testing of the stock and products we have received from the market have shown that a small proportion of the oxygen catheters from the aforementioned lot are closed and do not have a clear passage.

This closed catheter means that it may disconnect from the connector or can trigger an alarm on a connected device.

We are not aware of any cases where a patient, user or third party has been harmed.

Cause

It is suspected that the cause is the assembly (gluing) of the step adapter with the catheter tubing.

Measures to be taken by users and distributors

Please do not use any of the products from this affected batch and lock away any remaining stock.

Please prepare any remaining stock for collection and inform us so that we can organise the return.

For our records, please fill in the attached form Recall Response and send/fax it to us at:

ASSAmed GmbH
Münchwieser Str. 4
D-66450 Bexbach

Tel. ++49 (0) 6826-81155; Fax ++49 (0) 06826-81188

Please ensure that in your organisation all users of the aforementioned product and any other individuals who need to be informed are aware of this **Urgent Safety Information**. If you have sent the products to third parties, please pass on a copy of this information or inform the contact person listed below.



Please keep this information until you have taken these steps.

The Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute of Drugs and Medical Devices) has received a copy of this "Urgent Safety Information".

Contact: [REDACTED] Telephone: ++49 (0) 6826-81155, Fax: ++49 (0) 6826-81188

We regret this incident and thank you for your understanding and cooperation in this matter.

Yours faithfully

ASSAmed GmbH

Safety Officer



Recall response
Field Safety Corrective Action

Fax: ++49 (0) 6826-81188

Product recall

Product: Oxygen catheter; REF and Lot: see table

Article description	REF	Lot
Oxygen catheter CH10 with step connector and compress	SKKS.10	226.808; 255.809; 334.811; 344.812

We have the following number of affected products in stock:
(Please do not use products and return them to ASSAMED)

Quantity	REF	Article description	Lot
	SKKS.10	Oxygen catheter CH10 with step connector and compress	
	SKKS.10	Oxygen catheter CH10 with step connector and compress	
	SKKS.10	Oxygen catheter CH10 with step connector and compress	
	SKKS.10	Oxygen catheter CH10 with step connector and compress	

The signatory confirms

- that he/she no longer has any of the products listed above,
- that he/she has not passed on products to third parties,
- that he/she has informed third parties of the recall, if they have received recalled goods from him/her,
- that he/she will return all of the aforementioned products that he/she still holds or that are held by third parties to the manufacturer in accordance with their instructions.

Sender: _____

Contact: _____

Tel. No. _____

Comment: _____

Please proceed as follows:

1. Complete recall response, even if you no longer have products in stock.
2. Return completed form by fax to: **++49 (0) 6826-81188**

Date

Signature / Function / Company stamp

Please fax this form as soon as possible.