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Capitale Sociale € 98.800,00 interamente versato

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Urgent Field Safety Notice

Device: DEAS Autofeed Humidification Chamber

REF numbers:
04314 NS
04314

LOT numbers:
This notice is relevant to any Lot from 184612 up to and including 193723:

Manufacturer: DEAS S.r.l.

FSCA-identifier: 2019-266 **Date:** 10/10/2019

Attention: Medical Device Safety Officers (MDSO)

Distribution: All Critical Care clinical staff, managers and users of the above products

Type of action: Users of the products and lot numbers listed above must follow the additional instructions described below before use.

Description of the problem: We have received an isolated report showing that the floating system of our disposable autofeed humidification chamber REF 04314 NS Lot 184671 failed. Water overfilling occurred.
The root cause is: a violent impact, following a drop of the product, presumably during the putting into use phase (unpacked product) caused the disconnection of an element of the floating system.

Transmission of this Field Safety Notice:
This notice should be transmitted to all those who need to be aware within your organisation, or to any organisation where these potentially affected devices have been transferred.

DEAS apologises for any inconvenience this may cause. If you have any questions, please contact your distributor.

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The relevant National Authorities have been advised about this Field Safety Corrective Action.

Please maintain awareness of this Field Safety Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Action to be taken by the distributor and the user:

- Take note of the enclosed IFU stating the following additional warnings:
  - DO NOT use the chamber if it has been dropped;
  - Before starting ventilation, make sure the water level is not above the black maximum fill line.
- Complete the Urgent FSN Response Form to be forwarded to us, to confirm receipt of our FSN;
- Make sure that our FSN is passed on to all those who need to be aware of it within the organization or to any organisation where these potentially affected products have been transferred;
- Maintain awareness of our FSN and resulting action for an appropriate period to ensure effectiveness of our corrective action.

Corrective Action being taken by manufacturer DEAS:

Inform users about new warnings "DO NOT use the chamber if it has been dropped" and "Before starting ventilation, make sure the water level is not above the black maximum fill line".

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Domenico Scardovi, Quality Manager, DEAS S.r.l.

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Urgent Field Safety Notice Response Form

Confirmation of receipt

I / We confirm receipt of the Field Safety Notice relating to DEAS disposable Autofeed Humidification Chamber.

Product REF Numbers: **04314 NS**
04314

I / We will ensure that:

- all necessary personnel will be made aware of this notice;
- maintain awareness of this FSN and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Name of Organisation / Hospital: _____

Department: _____

Name and Title: (please print) _____

Signed: _____

Date: _____

Please return this form as soon as possible to:

DEAS S.r.l. Customer Service

Fax: +39 0546 54706

Or email: deas@deasnet.it

THANK YOU