

Urgent Field Safety Notice

Commercial name of the affected product: ala®purple
FSCA-identifier: 21.12.2015
Type of action: Recall

Date: December 21th 2015

Sender: alamedics GmbH & Co.KG, Hauffstrasse 21, D-89160 Dornstadt

Attention: distributor and user of ala®purple

Details and Identification of the affected devices:

ala®purple	AV240314	PN: 121001
	AV120215	PN: 121001
	AV120315	PN: 121001
	AV150415	PN: 121001
	AV230114	PN: 121002
	AV100614	PN: 121002
	AV131014	PN: 121002
	AV120215	PN: 121002
	AV120315	PN: 121002
	AV150415	PN: 121002

Description of the problem:

Due to vigilance reports in connection with the application of ala®purple from a Swiss hospital the Swissmedic has taken up investigations.

Swissmedic comes to the conclusion that the product ala®purple is not in accordance with the requirements of Directive 93/42/EEC. Swiss Medic considers the non-compliance due to the assessment of the documents proofing the biocompatibility submitted under the registration. The documentation generated by the manufacturer for determining the temperature range for the storage and transport of the product in the range of 5 ° C to 40 ° C is also classified as insufficient and thus as non-compliant.

Alamedics, due to the assessment by Swissmedic, calls back all batches of the product ala®purple throughout the CE area as well as in Switzerland and Turkey.

Advise on action to be taken by the user:

- Immediate identification of ala®purple devices on site of the customer
- Immediate quarantining of all ala®purple devices on site of the customer (no further usage)
- Immediate return of all ala®purple via the local distributor to alamedics GmbH & Co. KG
- Immediate filling of the 'Confirmation from to be sent back to the manufacturer'

Transmission of this Field Safety Notice:

This notice needs to be passed onto all those who need to be aware within your organisation or to any organisation (customers) where the potentially affected devices have been transferred.

Provided that you delivered the products to a third party, please forward a copy of this information or inform the contact person stated below.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice on the resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

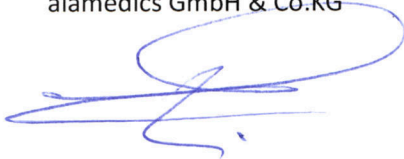
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

With kind regards,

alamedics GmbH & Co.KG



Dr. Christian Lingenfelder, CEO