Field safety notice mMD_20241021_01

machineMD
Based on TEM-512-01 Field safety notice

Date: 21.10.2024

FSN code: mMD_20241021_01

Swissmedic Ref: Vk_20241022_18

Urgent Field Safety Notice

neos

This document contains important information regarding the continued use of your medical device.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Customers and distributors

The Class I version of Neos will be recalled and replaced by the Class IIa version of the device.

This URGENT Field Safety Notice is intended to inform you about the recall of the medical device Neos, Class I and its replacement by Neos, Class IIa.

No health/safety issue have been detected, nor is the intention of this FSN to communicate a health/safety issue.

machineMD has decided to recall the Class I version of Neos following the certification of the company, including the new Class IIa version of the device, by TüV SüD Danmark ApS (NB 2443). machineMD will substitute all the class I Neos devices currently placed on the market in Switzerland by the Class IIa version of the device.

Hazard/harm associated with the issue

No hazard nor harm detected nor communicated.

Identification of affected systems

Appendix A to this letter provides a table with the references/types, model description and serial numbers of the affected devices being recalled.

Actions that should be taken by the customer

Please fill in the Response form and send it back to machineMD within 30 days.

machineMD will get in touch with you to carry out the recall. In case of any questions, please reach out to your machineMD representative directly.

Actions planned by machineMD to resolve the problem

machineMD will contact you within 2 weeks of this communication in order to plan and carry out the recall. Your device will be substituted by a class IIa Neos device.

This notice has been reported to the appropriate Regulatory Agencies.
Please be assured that maintaining a high level of safety and quality is our highest priority.

Sincerely,

Sara Silvano, Head of RA

Electronically signed by: Sara Silvano

Keep this Field Safety Notice!

Please complete and return the attached response form to machineMD promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken. If you need additional information or support concerning this issue, please contact your local machineMD representative.

URGENT Field Safety Notice Response Form

Instructions: Please complete and return this form to machineMD promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the recall, and required actions to be taken. It is important that your organization acknowledge receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Field Safety Corrective Action.

Reference: **insert FSN CODE :**

machineMD has decided to recall the Class I version of Neos. All the Class I Neos devices will be substituted by machineMD with a Neos class IIa device.

Customer/Consignee/Facility Name:

Street Address:

City/State/ZIP/Country:

Customer Actions:

- Please contact your local machineMD representative to plan and carry out the recall as soon as possible.
- Keep this Field Safety Notice and the Instructions for Use with the documentation of the device.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this letter has been properly distributed to all members of your staff who need to be aware of the contents of this communication.

Name of person completing this form:

- Signature:
- Printed Name:
- Title:
- Telephone Number: Email Address:
- Date (DD / MMM / YYYY):

Please send back this form to regulatory@machinemd.com

APPENDIX A

Product information to identify

Description

Device	Class	Basic UDI	Affected S/N
neos	Class I	7649989541-neos-0XX-F5	N10003
			N10004
			N10007
			N10009
			N10010
			N10011
			N10012

			N10015
			N10016
			N10018
			N10022
			N10023
			N10024
			N10028