inomed Medizintechnik GmbH · Im Hausgrün 29 · D-79312 Emmendingen

To whom it may concern

Your contact: Saschka Busch
Department: Vigilance
Tel.: +49 7641 94 14 - 0
Fax: +49 7641 94 14 - 94
E-Mail: vigilance@inomed.com
Website: www.inomed.com

Date: 2023-09-14

Urgent Field Safety Notice and voluntary product recall

Dear customer,

Following reports of our customers, inomed Medizintechnik GmbH is conducting a voluntary corrective action, issuing a precautionary product recall for further investigation of a potentially affected production batch.

The following item(s) with serial number(s) potentially affected in your facility are:
Article no.: 217200
Description: C3 CryoProbe 2,1mm sharp

Serial Nr.:
20B157, 20B159, 20B160, 20B161, 20B163, 20B166, 20B203, 20B206, 20B207, 20B208, 20B209, 20B210, 20B211, 20C003, 20C004, 20C005, 20C006, 20C009, 20C010, 20H108, 20H109, 20H110, 20H111, 20H112, 20H113, 20H114, 20H115, 20H117, 21A247, 21A248, 21A250, 21A251, 21A252, 21A253

As of now, we cannot fully rule out a batch-related manufacturing issue, hence
we strongly advise you not to continue using these affected items.

Regarding the previously affected products, it was observed that under significant mechanical bending stress, the stability of the probe tip could be compromised. This poses a risk of the probe tip breaking during such a handling.

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79312 Emmendingen
Germany
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Fax: +49 7641 94 14 - 94
info@inomed.com
www.inomed.com

Authorised Representatives:
Mariusz Gruchala, Jörg Wipfler
Register place Freiburg
HRB 260788
VAT no. DE 141 993 531
Tax no. 05019/24280
WEEE-Reg. no. DE 55946849

National bank details:
Sparkasse Freiburg-Nördlicher Breisgau
Account 2000 34 27
BIN: 680 501 01
BIC: FRSP DE 66
IBAN: DE 30 68050101 0020003427

International bank details:
Commerzbank Freiburg
Account 150 80 3500
BIN: 680 400 07
BIC: COBADEFF
IBAN: DE39 68040007 0150803500

Please identify and return any affected probes to us or your local representative if they are still at your facility. We will conduct a full service and if necessary, repair or replace returned products. Your local representative or our customer service department will get in touch with you regarding this matter after we have received the product. Please complete the form further below.

Best regards

inomed Medizintechnik GmbH
Saschka Busch

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Urgent Field Safety Notice
Voluntary Recall for
C3 CryoProbe

Please complete this form and return it to vigilance@inomed.com.

If you have any questions on completing or return of this form, please contact us as soon as possible.

Confirmation and disclosure form

I have read this Medical Device Field Safety Notice and understand its contents.
I will return all articles, which are affected of this Field Safety Notice:

Returned serial numbers: _____

Discarded serial numbers: _____

Name: _____

Position: _____

Healthcare facility / Distributer: _____

Email address: _____

Phone number: _____

Date: _____

Signature: _____

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