WEINMANN Emergency Medical Technology GmbH + Co. KG
PO Box 57 01 53 • 22770 Hamburg • GERMANY

Company
Name
Address
Zip code City
Country

February 18, 2018

Important safety notice:
Field safety corrective action on a medical device

Defective device information labels:

MEDUMAT Transport, MEDUMAT Standard and Standard[a], MODUL Oxygen and Combi and ULM CASE Dressing Box, Basis, Baby and Circulation

Dear Customers,

Quality and safety are our top priority, which is why we would like to act swiftly and transparently as usual and **ask you for your support in implementing this corrective action**.

Addressees
Users and owners/operators of the above-mentioned products as well as specialist dealers.

Medical devices affected

- MEDUMAT Transport (WM 28415 and WM 28315)
- MEDUMAT Standard[a] (WM 22810)
- MEDUMAT Standard (WM 22510)
- MODUL Oxygen (WM 22175) and MODUL Combi (WM 22177)
- ULM CASE Dressing Box (WM 8715)
- ULM CASE Basis (WM 8635)
- ULM CASE Baby (WM 3693)
- ULM CASE Circulation (WM 5225)

We have been able to identify precisely the serial numbers affected and **unfortunately products you ordered are affected.**

Description of problem
The printing of the device information labels is not wipe-resistant. This can lead to the print being lost and regulatory information about the medical device no longer being visible.

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www.weinmann-emergency.com

Center for Production, Logistics, Service
WEINMANN Emergency
Medical Technology GmbH + Co. KG
Siebenstücken 14 • 24558 Henstedt-Ulzburg
GERMANY

Business Management
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte

Registration Court
Hamburg Municipal Court
Dept. A # 115967
V.A.T. # DE288367727
WEEE Reg. # DE 47913245

Creditor ID
DE35ZZZ00000353971

General Partner
WEINMANN Emergency
Management GmbH, Hamburg

Registration Court
Hamburg Municipal Court
Dept. B # 38144

Certified QM System meeting
EC directive 93/42/EEC, Annex II
(EN ISO 9001/EN ISO 13485)

Banking Connections

Deutsche Bank AG Hamburg
IBAN DE87 2007 0000 0646 9639 00
SWIFT DEUTDEHH

Hamburger Sparkasse AG
IBAN DE44 2005 0550 1032 2626 67
SWIFT HASPDEHHXXX

Commerzbank AG Hamburg
IBAN DE14 2004 0000 0632 0071 00
SWIFT COBADEHHXXX

Cause
Both Production and Service used an ink ribbon which is not wipe-resistant to print the device information labels.

Remedy
Enclosed with this letter is a device information label with wipe-resistant printing for each of your affected products to satisfy the regulatory requirements (exception: ULM Case - more details on this can be found further on in this letter).
Furthermore, you will find instructions for affixing the labels in question and a list of the products whose device information labels need changing.
If a device information label is found to be illegible and it is thus impossible to assign the correct device information label, please contact After-Sales Service directly.

The Bundesinstitut für Arzneimittel und Medizinprodukte [BfArM – German Federal Institute for Drugs and Medical Devices] has been informed about the process.

As a user, owner/operator, specialist dealer or service partner you must now...

- ... use the attached reply form to confirm receipt of this letter and that it has been passed on, if appropriate.
- ... read and follow the instructions for replacing the device information labels.
- ... if you ordered ULM CASEs with the serial number groups below in the period between October 5, 2018 and December 17, 2018, please contact our After-Sales Service so that we can send you the correct labels:
-
    - ULM CASE Dressing (WM 8715) 11314 - 11436
    - ULM CASE Basic Equipment (WM 8635) 11347 - 11498
    - ULM CASE Baby (WM 3693) 11308 - 11505
    - ULM CASE Circulation (WM 5225) 10821 - 10832

- ... use the enclosed confirmation letter to report device-specific replacements to us.
- ... contact After-Sales Service directly if a device information label is illegible and it is impossible to assign the correct device information label.
- Please ensure that **this safety notice is brought to the attention of** all users of the above-mentioned products and of other people to be informed in your organization.

As a specialist dealer you must now also...

- ... please forward a copy of this letter, including the specific device information labels, on to your customers if you passed the above-mentioned products on to third parties.
- ... use the “Replacement of device information labels” form to confirm to us the devices on which you have replaced device information labels.

Contact
If you have any questions, we are of course happy to assist. If necessary, please feel free to contact your Area Manager or our After-Sales Service, telephone: +49 40 88 18 96 - 122,
e-mail: AfterSalesService@weinmann-emt.de.

Kind regards,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

André Schulte
Managing Director

p.p. Dennis Horstmann
Head of Supply Chain and Quality Management

Report form

Safety notice relating to defective device information labels, January 2019

Original letter sent to:
Company
Name
Address
Zip code City
COUNTRY

Please complete this reply form in full and send it by fax, e-mail or post to:

Fax: **+49 40 88 18 96 - 25492**
e-mail: **vigilance@weinmann-emt.de**

Post: **WEINMANN Emergency Medical Technology GmbH + Co. KG**
Safety Officer for Medical Devices
Frohbösestraße 12
22525 Hamburg
GERMANY

Please complete in full in block capitals:

☐ **Company details are identical to those of the addressee above.**

☐ **Company details differ from those of the addressee as follows:**

Your customer no.: _____

Company + address: _____

_____

_____

☐ **I hereby confirm receipt of this letter** and that I **have read and understood its contents**. **This letter has been brought to the attention of all users of the product and of other people in my organization who need to be informed**.
If products have been passed on to third parties (applies to specialist dealers, for example), a **copy of this information has been passed on to them**.

_____
Date, signature

_____
Name (in block capitals)

_____
Position (in block capitals)

_____
e-mail (in block capitals)