

medimex GmbH | In den Fritzenstücker 9–11 | D-65549 Limburg

Ihr Ansprechpartner

Karina Damm

Kundenservice medimex

fon: +49.6431.7302 128

fax: +49.6431.7302 235

mail: karina.damm@medimex.de

Datum: 26.05.2021

Urgent Security Notice - Recall

medimex Einmal-Handwaschbürste mit Nagelreiniger, trocken, steril (8M50200200)

Dear Sirs and Madames,

Unfortunately we have to inform you that we have received an urgent safety information from the manufacturer Nex Medical Antiseptics S.r.l. 20010 Casorezzo (MI) Italy about goods that we have delivered to you. The products were sold as private label products from the manufacturer medimex GmbH until August 2020 and then sold on the market as an own-brand label product (manufacturer: Nex Medical Antiseptics S.r.l., distribution: medimex GmbH).

Nex Medical Antiseptics S.r.l. was informed by "Steril Milano", one of its sterilization suppliers, of a potential risk associated with incorrect sterilization for some batches.

The use of non-sterile medical devices in a clinical setting can increase the risk of infection, which can cause serious damage. So far, Nex Medical Antiseptics S.r.l. received no indication of adverse events or serious harm to patients that could be associated with this site safety measure.

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Safety Information. If you have given the products to third parties, please forward a copy of this information or inform the contact person given below.

Furthermore, we must please you to block all stocks of the affected batches and no longer use them.

Hausanschrift

In den Fritzenstücker 9–11
65549 Limburg
fon: +49.6431.7302 300
fax: +49.6431.7302 235
mail: kontakt@medimex.de
internet: www.medimex.de

Bank

Commerzbank AG Limburg
IBAN: DE22 5138 0040 09 362 15 000
BIC: DRESDEFF513
Gläubiger ID: DE78ZZZ00000149691

Handelsregister

AG Limburg HRB 4389

USt.-IdNr. DE265479685

Geschäftsführer Marcus H. Simon

Please find attached the list of the affected batches.

We ask you to fill out the response form accordingly and send it back by fax or email by June 15, 2021 at the latest.

FAX:06431-7302-235

Email: karina.damm@amefa-med.com

Affected products:

Ref.	Article name	Affected batch
8M50200200	medimex Einmal-Handwaschbürste mit Nagelreiniger, trocken, steril	ND0597, ND0713, NE0168, NE0636, NE0637, NE0869, NF0326, NF0797, NF0798, ED0610

We apologize for the inconvenience.

Best regards

i.A Karina Damm

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REPLY FORM
PLEASE FAX / MAIL BACK TO MEDIMEX GMBH!

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Please fill out this confirmation of receipt completely and tick the appropriate boxes. Please also inform us in the case that you no longer have any of the listed medical devices / product families.

- ☐ We confirm the receipt of this safety instruction in the field and confirm the implementation of the following measure (s): Blocking of the batches - return to medimex GmbH
- ☐ We confirm the receipt of this safety instruction in the field and have the following quantities of the affected products / batches ready for collection.
- ☐ We confirm receipt of this safety instruction in the field and do not have any of the affected products in-house.
- ☐ I have read the information from May 27th, 2021 and informed all relevant persons about the product recall and the described procedure.

Batch	Affected amount

Customer name / department	
Address / zip code / city	
E-Mail- address	
Phone number	

date

signature / printed name

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