

Fuhrmann GmbH · Bövingen 139 · D-53804 Much

Addressee

Contact person:

Name

phone. +49 2245-91 96-33

fax +49 2245-91 96-60

qw@fuhrmann.de

SRN Nummer: DE-MF-000006652

Date

Safety information – Ear-patch, white, non-sterile (REF 10994.)

Dear Sir or Madam,

for reasons of patient safety, we have to inform you about the following safety information.

Description of the problem

The label of the above-mentioned product of the relevant batches has an incorrect manufacturing date and therefore indicates a longer shelf life on the label than the actual shelf life. The shelf life is incorrectly extended by 3 months.

Potential hazards and possible risks for patients, users (operators) or third persons

At present there are no risks for patients, because the actual shelf lives (02.2026 and 03.2026) have not exceeded yet and the products can be used until this date. If the products are used until this date there are no risks for patients, users (operators) or third persons.

Kontakt

Fuhrmann GmbH
Bövingen 139
D-53804 Much

Telefon +49 2245 9196-0

Fax +49 2245 9196-60

www.fuhrmann.de • info@fuhrmann.de

Geschäftsführung

Arndt Fuhrmann

Handelsregister 41 HRB 2474

Amtsgericht Siegburg

Ust-IdNr. DE123108396

Steuer-Nr. 220/5804/0316

Bankverbindung

Postbank Köln

BIC: PBNKDEFF370 • IBAN: DE70 3701 0050 0730 7955 01

Raiffeisenbank Kürten-Odenthal

BIC: GENODED1RKO • IBAN: DE08 3706 9125 0010 1190 14

Kreissparkasse Köln

BIC: COKSDE33XXX • IBAN: DE50 3705 0299 0005 0005 42

The following products that have been delivered to you are affected:

REF	Name	LOT	UDI	quantity delivered
10994.	Ear-patch, white, non-sterile	40026827 40026915 40027011	-	

What measures are to be taken by the addressee

1. Please immediately check your stock and immediately isolate the product listed above.

If you have continued to distribute the product that is the subject of this safety information, please identify your other customers and inform the affected customer(s) of this safety information immediately. **If it can be ensured** that the customers concerned have received this safety information and the product will be used before 27.02.2026, it is not mandatory to return the products.

We would like to ask you to monitor and follow up the measures with your customers!

2. Complete the enclosed reply form in full and send it to the above address by post, e-mail, or fax by **10.02.2022**.

Please note: Please return the completed reply form even if you no longer have any remaining stocks of the product concerned. Due to legal requirements, we must ensure and document that you have received this information, and your reply serves as proof of this.

Kontakt

Fuhrmann GmbH
Bövingen 139
D-53804 Much
Telefon +49 2245 9196-0
Fax +49 2245 9196-60
www.fuhrmann.de • info@fuhrmann.de

Geschäftsführung

Arndt Fuhrmann
Handelsregister 41 HRB 2474
Amtsgericht Siegburg
Ust-IdNr. DE123108396
Steuer-Nr. 220/5804/0316

Bankverbindung

Postbank Köln
BIC: PBNKDEFF370 • IBAN: DE70 3701 0050 0730 7955 01
Raiffeisenbank Kürten-Odenthal
BIC: GENODED1RKO • IBAN: DE08 3706 9125 0010 1190 14
Kreissparkasse Köln
BIC: COKSDE33XXX • IBAN: DE50 3705 0299 0005 0005 42

Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods. We will only take back goods from the affected batch (see table above).

Pass on this safety information!

Please ensure that all relevant persons in your organisation are aware of this safety information. After a final assessment, the competent supervisory authority may also be informed about this measure.

We apologise for any inconvenience caused to you in connection with this safety information and thank you in advance for your support to enable this measure to be implemented quickly and effectively.

With best regards

Contact

Person Responsible for Regulatory Compliance according to article 15 MDR

Kontakt

Fuhrmann GmbH
Bövingen 139
D-53804 Much
Telefon +49 2245 9196-0
Fax +49 2245 9196-60
www.fuhrmann.de • info@fuhrmann.de

Geschäftsführung

Arndt Fuhrmann

Handelsregister 41 HRB 2474
Amtsgericht Siegburg
Ust-IdNr. DE123108396
Steuer-Nr. 220/5804/0316

Bankverbindung

Postbank Köln
BIC: PBNKDEFF370 • IBAN: DE70 3701 0050 0730 7955 01
Raiffeisenbank Kürten-Odenthal
BIC: GENODED1RKO • IBAN: DE08 3706 9125 0010 1190 14
Kreissparkasse Köln
BIC: COKSDE33XXX • IBAN: DE50 3705 0299 0005 0005 42

Annex

Safety information – Ear-patch, white, non-sterile (REF 10994.)

Affected REF/batches see cover letter.

Reply form

Upon receipt of your reply form, you will be contacted by our customer service team to arrange the return and, if necessary, replacement of the affected goods.

(Please tick!)

- We do not have any remaining stocks of the product concerned in stock.

- We have forwarded this safety information to all relevant users and can ensure that the products are used in accordance with this safety notice. A return shipment is not necessary.

- We have the following number of items in stock (please enter in the table below).
Only goods from the affected batches that are affected by this recall will be taken back or exchanged. Please do not return any goods unsolicited.

REF	LOT	Quantity (please specify number of pieces)

Name of the institution	
Street	
Postcode/ City	
Name of contact person (in block capitals)	
Email	

DateSignature