

Draft.

Urgent safety information

Please replace instructions for use

regarding

Product Track® Bleach

Type of measurement: Fiels safety corrective action

Pforzheim, 2023-05-17

Sender:

Bernhard Förster GmbH
Westliche Karl-Friedrich-Straße 151
75172 Pforzheim, Germany

Recipient:

Customers and distributors who have received affected batches of the product

Identification of affected medical device:

Ref. Number: -408-0610
Track Bleach 1,0x125mm
Affected batches: 11562 ; 11769 ; 11413

Description of the problem including the determined cause:

With said batches, we delivered a set of instructions for use which state conformity according to 93/42 EWG instead of EU 2017/745. This is the only difference in the instructions for use, the contents is identical, only the regulations differ.

What measures are to be taken by the addressee?

Replacement of the IFU with the new ones provided by Bernhard Förster GmbH.
Sending of the receipt form, see attachment of this letter.

Forwarding of the information described here:

Please make sure that all users of the product(s) listed above and all other affected persons have knowledge of this urgent safety information. If you gave product(s) to third parties, please forward a copy of this information to them or inform the responsible person named below.

Keep this information at least until the conclusion of the measures, please.

The regulatory authorities have received a copy of this urgent safety information.

Contact person:

Michael Fieß (Quality management representative)

Email: complaints@forestadent.com

Telefon: (+49) 7231 159 137

Available during office hours in Germany

Signature

Urgent safety information – receipt

Replacement of instructions for use

regarding

Track Bleach 1,0x125mm

- ☐ I hereby confirm that I have read and understood the urgent safety information above.
- ☐ I have forwarded this information to all third parties involved, including customers who have been affected.

Organisation / company: _____

Name, first name: _____

Place, date: _____

Signature: _____

Please fill in this form and return it via email to
complaints@forestadent.com