

Bernhard Förster GmbH · Postfach 660 · 75106 Pforzheim (Germany)

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

## Urgent safety information

***Please replace instructions for use***

regarding

Postfach 660  
75106 Pforzheim, Germany

Telefon (0 72 31) 459-0  
Telefax (0 72 31) 459-102  
E-Mail: info@forestadent.com

Ust-IdNr. DE 811 199 584

### Product Track<sup>®</sup> Bleach

Type of measurement: Field safety corrective action

*Pforzheim, 2023-07-27*

#### 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 ; 11918

#### 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.

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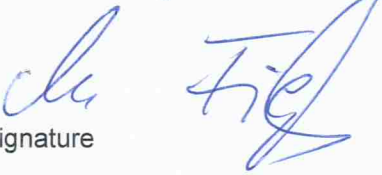
**Contact person:**

Michael Fieß (Quality management representative)

Email: [complaints@forestadent.com](mailto:complaints@forestadent.com)

Telefon: (+49) 7231 159 137

Available during office hours in Germany

  
Signature

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## 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](mailto:complaints@forestadent.com)