

Med4Trade GmbH ■ Thanhof 13 ■ D-93173 Wenzenbach

Med4Trade GmbH  
 Thanhof 13  
 D-93173 Wenzenbach/Regensburg  
 Tel. +49 (0)941/69 81 63-0  
 Fax+49 (0)941/69 81 63-99  
 info@med4trade.com  
 www.med4trade.com

Wenzenbach, 16.03.2023

### Urgent Safety Notice

## Contour next test strips, 25 packaging units (REF: 84507300)

Dear trading partner,

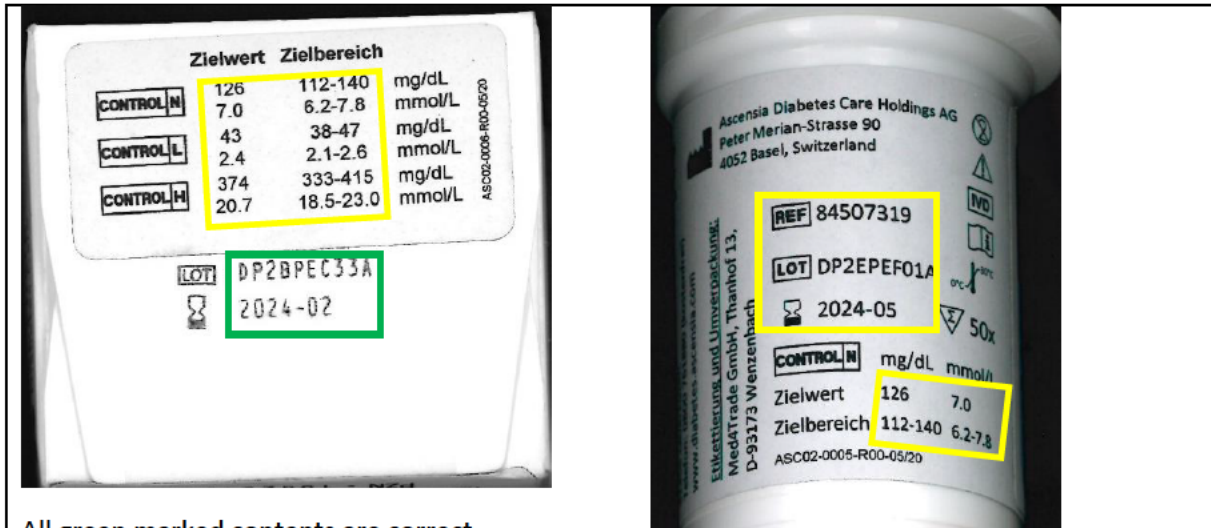
with this notice Med4Trade GmbH asks you on behalf of EvivaMed Handelsgesellschaft mbH to check over the lot numbers of the following product:

|                                   |   |
|-----------------------------------|---|
| <b>manufacturer:</b>              | Ascensia Diabetes Care Holdings AG  |
| <b>labelling and repackaging:</b> | Med4Trade GmbH on behalf of EvivaMed Handelsgesellschaft mbH (Thanhof 13, D-93173 Wenzenbach) |
| <b>trade name:</b>                | Contour next test strips, 25 packaging unit   |
| <b>REF:</b>                       | 84507300  |
| <b>lot number:</b>                | DP2BPEC33A  |

#### Description of the problem:

In this case of a small number of packages, it can not be excluded, that the following different labelling may apply:





All green marked contents are correct.  
All yellow marked contents are incorrect.

- Packaging unit incorrect on all labels:  
Correct packaging unit: 25 pieces, Wrong packaging unit: 50 pieces
- Target values and target areas incorrect on all labels:

|            | Correct target value | Correct target area | Wrong target value | Wrong target area |
|------------|----------------------|---------------------|--------------------|-------------------|
| Control N: | 125 mg/dL            | 111-139 mg/dL       | 126 mg/dL          | 112-140 mg/dL     |
|            | 7.0 mmol/L           | 6.2-7.7 mmol/L      | 7.0 mmol/L         | 6.2-7.8 mmol/L    |
| Control L: | 43 mg/dL             | 38-47 mg/dL         | 43 mg/dL           | 38-47 mg/dL       |
|            | 2.4 mmol/L           | 2.1-2.6 mmol/L      | 2.4 mmol/L         | 2.1-2.6 mmol/L    |
| Control H: | 367 mg/dL            | 326-407 mg/dL       | 374 mg/dL          | 333-415 mg/dL     |
|            | 20.4 mmol/L          | 18.1-22.6 mmol/L    | 20.7 mmol/L        | 18.5-23.0 mmol/L  |

- Incorrect labelling of the container: Lot number is incorrect:  
Correct lot number: DP2BPEC33A, wrong lot number: DP2EPEF01A
- Incorrect labelling of the container: Expiry date is incorrect:  
Correct expiry date: 2024-02, wrong expiry date: 2024-05
- Incorrect labelling of the container: REF-number is incorrect:  
Correct REF: 84507300, wrong REF: 84507319

**We ask you to check your stocks and destroy any remaining packages or send them back to EvivaMed Handelsgesellschaft mbH for credit note (postal charges will be refunded).**

**Address:**

EvivaMed Handelsgesellschaft mbH  
Thanhof 13  
D-93173 Wenzenbach

**Disclosure of the information described here:**

Please ensure in your organisation that all users of the above-mentioned product and other persons to be informed, are aware of this Urgent Safety Notice.

If you have given the products to third parties, please forward a copy of this information or inform the contact person below.

Please retain this information at least until the action is completed.

**A copy of this Urgent Safety Notice has been forwarded to Paul Ehrlich Institute.**

**Contact person:**

[REDACTED]  
Head of quality management and regulatory affairs

[REDACTED]

**Thank you for your support.**

**Best regards**

[REDACTED]

[REDACTED]

**Head of quality management and regulatory affairs**