

Date: 2025-09-19

**Field Safety Notice**  
**SEKUMATIC NDT**

For Attention of\*:Vigilance/Quality manager of the facility products.

Dear customer,

We are reaching out to inform you of an issue regarding the product Sekumatic NDT from the below list:

| Product       | SKU     | Batch Numbers                       |
|---------------|---------|-------------------------------------|
| Sekumatic NDT | 3124590 | Refer to table below in section 1.5 |

Following an internal check, we have realized that the products from this SKU have been delivered without the back label of the product. This back label provides information on precautions of use and pictograms, instructions for use and microbiological claims.

With incomplete labelling, users are not informed about warnings or proper product handling which may compromise device performance and/or patient or user safety.

“As a precautionary measure, we are releasing the attached Field Safety Notice to alert customers and kindly ask you to take the following actions”:

- Please do not use or distribute the identified products. If you have distributed these products to your customers, it is essential that you inform them about the issue and advise them to stop use or distribution.
- Complete the attached reply form: review the information in this document, follow the appropriate actions outlined in section 3, and confirm your understanding and compliance with the outlined measures. Please return the Customer Reply Form to us within four weeks after receiving the FSN. In case you have distributed the products to your customers, please collect their responses and complete a single reply form with aggregated data.

We sincerely apologize for any inconvenience this may cause and appreciate your understanding and cooperation in this matter.

Thank you for your cooperation and understanding.

Best regards,  
ECOLAB VIGILANCE

**Field Safety Notice (FSN)**  
**SEKUMATIC NDT**  
**MISSING BACK LABEL**

| 1. Information on Affected Devices* |                                                                                                                                                                                                                                                                                                                                                                               |         |                |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|----------------|
| 1.                                  | 1. Device Type(s)*                                                                                                                                                                                                                                                                                                                                                            |         |                |
|                                     | Medical device classified as Class IIa according to MDD.                                                                                                                                                                                                                                                                                                                      |         |                |
| 1.                                  | 2. Commercial name(s)*                                                                                                                                                                                                                                                                                                                                                        |         |                |
|                                     | SEKUMATIC NDT                                                                                                                                                                                                                                                                                                                                                                 |         |                |
| 1.                                  | 3. Unique Device Identifier(s) (UDI-DI)                                                                                                                                                                                                                                                                                                                                       |         |                |
|                                     | N/A                                                                                                                                                                                                                                                                                                                                                                           |         |                |
| 1.                                  | 4. Primary clinical purpose of device(s)*                                                                                                                                                                                                                                                                                                                                     |         |                |
|                                     | Concentrate. For use in the automated reprocessing of medical devices in washer-disinfectors, tunnel washers, and wash cabins. Use at a concentration of 0.5% to 2.0%, preferably in lukewarm to hot water, depending on the machine type. Observe the required concentrations and contact times. Rinse with tap water is required. Ensure material compatibility before use. |         |                |
| 1.                                  | 5. Device Model/Catalogue/part number(s)*                                                                                                                                                                                                                                                                                                                                     |         |                |
|                                     | Product                                                                                                                                                                                                                                                                                                                                                                       | SKU     | Country        |
|                                     | Sekumatic NDT                                                                                                                                                                                                                                                                                                                                                                 | 3124590 | Austria        |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 4204SN1602     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3275SN0403     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Bulgaria       |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2284SN1503     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3364SN1203     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3364SN1203     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3364SN1203     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Croatia        |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Slovenia       |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Czech Republic |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2174SN0302     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 4204SN1602     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2284SN1503     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 1135SN1503     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2205SN0603     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3175SN0803     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3275SN0403     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3364SN1203     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 5434SN1403     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Estonia        |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2284SN1503     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | Hungary        |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3393SN0601     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2174SN0302     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 2205SN0603     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3175SN0803     |
|                                     |                                                                                                                                                                                                                                                                                                                                                                               |         | 3364SN1203     |

|    |                                        |  |           |                                                                                                                            |  |
|----|----------------------------------------|--|-----------|----------------------------------------------------------------------------------------------------------------------------|--|
|    |                                        |  | Lithuania | 2174SN0302                                                                                                                 |  |
|    |                                        |  | Poland    | 1115SN1103<br>2174SN0302<br>2205SN0603<br>2284SN1503<br>3175SN0803<br>3364SN1203<br>3393SN0601<br>4204SN1602<br>5434SN1403 |  |
| 1. | 6. Software version                    |  |           |                                                                                                                            |  |
|    | N/A                                    |  |           |                                                                                                                            |  |
| 1. | 7. Affected serial or lot number range |  |           |                                                                                                                            |  |
|    | See Table point 1.5                    |  |           |                                                                                                                            |  |
| 1. | 8. Associated devices                  |  |           |                                                                                                                            |  |
|    | N/A                                    |  |           |                                                                                                                            |  |

| 2. Reason for Field Safety Corrective Action (FSCA)* |                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.                                                   | 1. Description of the product problem*<br>Following an internal check, we have realized that the products from this SKU have been delivered without the back label on the product. This back label provides information on precautions of use and pictograms, instructions for use and microbiological claims. |
| 2.                                                   | 2. Hazard giving rise to the FSCA*<br>With incomplete labelling, users are not informed about warnings or proper product handling which may compromise device performance and/or patient or user safety.                                                                                                       |

| 3. Type of Action to mitigate the risk* |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| 3.                                      | <b>1. Action To Be Taken by the END-USER*</b><br><br><input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification / inspection<br><br><input checked="" type="checkbox"/> Inform all users within your facility<br><br><input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None |                                                |
|                                         | <b>2. Action To Be Taken by the DISTRIBUTOR*</b><br><br><input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification / inspection<br><br><input checked="" type="checkbox"/> Inform all your customers<br><br><input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None          |                                                |
| 3.                                      | 3. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Immediately                                    |
| 3.                                      | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Yes<br>Within 4 weeks after receipt of the FSN |
| 3.                                      | <b>5. Action Being Taken by the Manufacturer*</b><br><br><div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Product Removal<br/> <input type="checkbox"/> Software upgrade<br/> <input type="checkbox"/> Other               </div> <div> <input type="checkbox"/> On-site device modification/inspection<br/> <input type="checkbox"/> IFU or labelling change<br/> <input type="checkbox"/> None               </div> </div>                                                                                               |                                                |

| 4. General Information* |                                                                                                                  |                                                     |
|-------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| 4.                      | 1. FSN Type*                                                                                                     | New                                                 |
| 4.                      | 2. For updated FSN, reference number and date of previous FSN                                                    | N/A                                                 |
| 4.                      | 3. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN)         |                                                     |
|                         | a. Company Name                                                                                                  | Ecolab Deutschland GmbH                             |
|                         | b. Address                                                                                                       | Ecolab-Allee 1, 40789 Monheim am Rhein, Deutschland |
|                         | c. Website address                                                                                               | www.ecolab.com                                      |
| 4.                      | 4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. |                                                     |
| 4.                      | 5. List of attachments/appendices:                                                                               | Appendix 1: Customer reply form                     |

| Transmission of this Field Safety Notice |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                          | <p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p> |

