

Documentation System

For **Steam**, **Ethyleneoxide**, **Formaldehyde** and **Hydrogen peroxide/Plasma** Sterilization processes



Product Description

The Documentation System consists of the following elements:

- Printer gun with a total of three lines of 12 digits each;
 - The first 4 digits of the first line can only be numeric and the rest alphanumeric.
 - With other lines only the number can be written.
- Labels for steam, ethylene oxide, formaldehyde and hydrogen peroxide (plasma) sterilization in accordance with EN ISO 11140-1 in different colors but all double adhesive labels with or without Indicator
- Documentation form; these labels and strip indicators from PCDs are attached to this form.

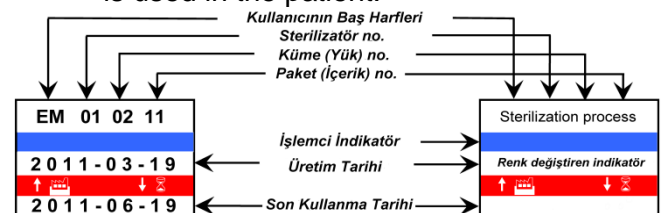
Instructions for use

The system uses a separate documentation sheet for each sterilizer every day. This documentation sheet contains all information about the test, such as cluster/batch numbers - production date - expiry date - sterilizer number - cluster contents and the name of the person responsible for cluster evacuation. The same information is printed on labels with indicators and double-sided adhesive with a printer gun. These labels are attached to the packages to be sterilized and to this form together with the strip indicators from the PCDs (see documentation form).

The implementation of the system is as follows:

1. Labels with indicators suitable for the sterilization method, one for each of the

- packages to be placed in the sterilizer (but two for one), are attached with a gun.
2. Start the sterilizer,
3. The documentation form for that sterilizer containing the date of that day is opened.
4. After the sterilization process is finished, two labels are applied to the package and one label is transferred to the documentation.
5. Packages are removed from the sterilizer and sent to the relevant departments.
6. Before the packs are used, their labels are transferred to the patient's file.
7. The label in the patient file is matched with the label in the documentation form to identify the source of any secondary infection that may occur in the future.
8. In this documentation form, the Sterilization Control Indicator (Batch Test) and (Bowie-Dick-Test-Strip if it is a steam autoclave) related to that cycle are observed to prove that STERILE material is used in the patient.



The information on the label enables the sterilization department to monitor/track all data and to prove that all standards and procedures have been followed and that all materials have been sterilized in accordance with the standards.

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Labels are produced for the following sterilization processes:

Sterilizasyon İşlemi	İndikatör rengi (işlemden önce)	İndikatör rengi (işlemden sonra)
Buhar		
Etilen oksit		
Formaldehit		
Hidrojen Peroksit (Plasma)		

Background information:

The European Medical Device Directorate (MDD) requires a documented traceability procedure for the production of sterile products for human use, whether they are manufactured for commercial or in-hospital patient use. The EN ISO 9001 Standard and EN 550-554, ISO 14937 and ISO 17665 recommend the control and documentation of sterilization processes. Each batch or batch produced must have documentation showing that all parameters that may affect sterilization have been fulfilled and completed, and this documentation must include a specific batch number.

Advantages

- There is no increase in documentation related to patient follow-up.
- Fewer errors in cluster/party registration
- Tracking system without duplicating worksheets
- 4 different label colors allow quick sorting of products according to the first-in-first-out (FIFO) principle
- Labels with process indicators do not require the use of extra process indicators (autoclave tape, etc.) for each pack
- Labels are available for Steam, EO, Formaldehyde and Hydrogen Peroxide-Sterilization processes.
- Low cost

Description and Content	Order No.
ABGIndicators® 3-Line Double Adhesive Blue Label with Purple Vapor Indicator , 750 ± 3 pcs per 1 roll. 8 rolls in 1 package. 1 Stamp free on purchase of 16 Rolls	234-240-872
ABGIndicators® 3-Line Double Adhesive Green Label-ECO with Purple Vapor Indicator , 750 ± 3 pcs per 1 roll. 8 rolls per 1 pack. Without Stamp	234-000-872
ABGIndicators 3-Line Double Adhesive Red Label without Indicator , 1 Stamp free with purchase of 16 Rolls	234-240-863
ABGIndicators® 3-Line Double Adhesive Pink Label-ECO without Indicator , 750 ± 3 pcs per 1 roll. 8 rolls in 1 pack. Without Stamp	234-000-863
3-Line Double Adhesive, Purple label with Blue EO Indicator , 12 rolls in 1 pack, each with 750 ± 3 pcs +1 liner stamp	235-242-875
3-Line Double Adhesive Yellow FO Red label with Indicator , 12 rolls in 1 pack, each with 750 ± 3 pcs +1 liner stamp	235-243-874
3-Line Double Adhesive Turquoise label with Purple H2O2 Indicator , 12 rolls in 1 pack, 750± 3 pcs each +1 liner stamp	235-244-871
Gündem®-Labeller 3 Line, 12 Columns, 1st line all Alpha numeric. + 1 Name stamp. https://www.youtube.com/watch?feature=player_embedded&v=20dIsNpnRUC	232-130-010
Gündem® Stamp; Black for Printer guns No. 232-130-010.	232-130-030

%100 Yerli Sermaye

Üretici / Manufacturer / Producteur:

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Page 2 / 2

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