Documentation System

FOR STEAM, ETHYLENE OXIDE, FORM-ALDEHYDE AND HYDROGEN PEROXIDE STERILIZATION PROCESSES

Application

The documentation system is used for patient-related traceability of all medical sterilization processes. The documentation sheet contains all necessary information to release a sterilization batch. For one sterilizer and day, one documentation sheet is used (see page 3). Using a labeling device the documentation sheet and each sterile packing can be labeled with a self-adhesive label that contains the following information: production and expiry date, responsible person, content of the pack, sterilizer and batch number (see figure “recommended label content” next page). All packs in the batch and the documentation sheets have the same label content and batch number.

After opening the sterile pack in the operation room the label can be peeled off and adhered to the patient and/or operation-related documentation. The content of the label allows patient related tracing back to the batch-related documentation in the sterilization department. In case of a nosocomial infection the sterilization data is available to exclude that the infection was caused by non-sterile instruments.

Labels without and with indicator for steam sterilization processes are available in four colors: red, green, blue and yellow. Different colors allow staff to differentiate sterile goods from different production periods, enabling a correct First In/ First Out (FIFO) storage handling system.

Product Description

The documentation system consists of the following components:

1. Hand-labeler containing three printing lines with 12 digits each, available in the following two versions:
   - The first three digits of the first line can print alphanumeric digits, the remaining ones print numbers (art-no. 240-820).
   - The first line can print alphanumeric digits (art-no. 240-830).

   The remaining two printing lines allow production and expiry date documentation.
2. Selection of self-adhesive and double self-adhesive labels with or without type 1 process indicators according to EN ISO 11140-1 for steam, ethylene oxide, formaldehyde and hydrogen peroxide/plasma sterilization processes.
3. Documentation sheet to adhere indicator strips from PCDs and the labels

Sterilization processes

The labels have two horizontal colored bars. For labels with process indicator the bar above contains indicator substrate, which changes color during sterilization.

Sterilization process	Indicator color (without penetration)	Indicator color (with penetration)
Steam		
Ethylene oxide		
Formaldehyde		
Hydrogen peroxide/plasma		

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Background Information

The European Medical Device Directive (MDD) requires for reprocessing of medical devices to use appropriate validated procedures and to document the results of the validation process and routine monitoring. The quality management standard for medical devices (EN ISO 13485) and the validation standards of all sterilization processes (e.g. EN ISO 14937, EN ISO 17665-1 etc.) require monitoring and documentation of all relevant sterilization process parameters. This documentation is required for the production or reprocessing of all medical devices independent of where they are sterilized. For each individual load a batch number is required associated with all relevant parameters used in the sterilization process.

It is required, that all sterile packs have to be labeled with a type 1 process indicator according to EN ISO 11140-1 to ensure that the packs have passed the sterilization process and can be differentiated from non-sterilized packs.

The documentation labels with process indicators are available for different sterilization processes (see above color chart) and make the use of an additional process indicator (e.g. autoclave tape) obsolete.

If a sterilizer with two doors is used and one door opens in the storage room, labels without process indicators can be used under the condition that the door opens only after the sterilizer program has checked the correct process conditions.

Benefits

- Easy print of identical labels with minimum time and effort.
- Eliminates mistakes in batch numbers.
- Easy trace back system without additional effort.
- The self-adhesive label offers patient-related documentation without additional paperwork.
- Innovative product design and manufacturing process provides a cost-effective indicator.
- Easy interpretation of the results due to precise color change.
- No need for additional process indicators using for labels with indicator.
- The expiry date can be marked using different background label colors.
- Less time wasted in the CSSD- and/or OR-department.
- The label contains a specified type 1 chemical indicator according to EN ISO 11140-1.
- Environmentally friendly, all chemical indicators are protected from bleeding by a polymer binder and surface coating and can be disposed with normal garbage.
- The indicator color chemistry is a non-reversible chemical reaction. The indicator strip can be a documented proof for several years without changing back to its original color.

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FOR THE MONITORING OF STERILIZATION PROCESSES

Sterilizer No.: 01 Sterilization department: University Hospital CSSD

Date: 2023-03-03

Sterilization process: ☒ Steam ❑ Ethylene Oxide ❑ Formaldehyde ❑ Hydrogen Peroxide

Bowie-Dick-Simulation Test (BDS) ❑ not applicable (no BDS-Test required)

BDS-Test indicator strip	Test O.K.?		Responsible User
GKE	☒ yes	❑ no	J. Example

Process | Batch Monitoring System*

Adhere GKE documentation labels or complete form manually.

User-,sterilizer-and batch number	JE 1234 56 GKE 1		JE 1234 56 GKE Steri-Record 2		JE 1234 56 GKE Steri-Record 3			4
Production Date	2023-03-03		2023-03-03		2023-03-03			
Expiry Date	2023-06-03		2023-06-03		2023-06-03			
Adhere indicator strip	GKE		GKE		GKE			
Program	Universal		Universal		Universal			
Temperature Sterilization Time	134 °C	8:05 h	134 °C	9:15 h	134 °C	10:45 h	°C	h
Test O.K.?	☒ yes	❑ no	☒ yes	❑ no	☒ yes	❑ no	❑ yes	❑ no
Signature	J. Example		J. Example		J. Example			

User-,sterilizer-and batch number			5			6			7			8
Production Date												
Expiry Date												
Adhere indicator strip												
Program												
Temperature Sterilization Time	°C		h	°C		h	°C		h	°C		h
Test O.K.?	❑ yes	❑ no		❑ yes	❑ no		❑ yes	❑ no		❑ yes	❑ no	
Signature												

*Package monitoring indicators are filed in the patient documentation.

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Order Information

The labeling device is available in two different versions:

Art. No.	Product Code	1st printing line	2nd + 3rd printing line
240-820	D-G-NL	3 alphanumeric digits and 9 numeric digits	12 numeric digit
240-830	D-G-AL	12 alphanumeric digits	

Self-adhesive 3-line labels without or with process indicator

Art. No.	Product Code	Color	Sterilization Process
230-864	D-L-SA-Y	Yellow	Without indicator for all processes except hydrogen peroxide
230-872	C-S-L-1-SA-B	Blue	Steam
230-874	C-S-L-1-SA-Y	Yellow	Steam

Double self-adhesive 3-line labels without or with process indicator

Each package contains rolls of 750 double self-adhesive labels with one ink roll.

Art. No.	Product Code	No. of rolls/pack	Color	Sterilization Process
240-853	D-L-DA-R	4	Red	Without indicator for all processes except hydrogen peroxide
240-861	D-L-DA-G	12	Green	
240-862	D-L-DA-B		Blue	
240-863	D-L-DA-R		Red	
240-864	D-L-DA-Y		Yellow	
240-871	C-S-L-1-DA-G	12	Green	Steam
240-872	C-S-L-1-DA-B		Blue	
240-873	C-S-L-1-DA-R		Red	
240-874	C-S-L-1-DA-Y		Yellow	
240-883	C-S-L-1-DA-R	4	Red	
242-875	C-E-L-1-DA-P	12	Purple	Ethylene oxide
242-885		2		
243-874	C-F-L-1-DA-Y	12	Yellow	Formaldehyde
243-884		2		
244-873	C-F-L-1-DA-Y	12	Red	Hydrogen peroxide/plasma
244-883		2		

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