CLEANING
STERILIZATION

Product Catalogue

Chemical indicators, PCDs and accessories for cleaning and sterilization

Bowie-Dick Simulation Test
Batch and Process Monitoring Systems, Documentation System

Sterilization Processes: Steam | Formaldehyde | Hydrogen Peroxide | Ethylene Oxide
Cleaning Processes

Table of Content

Bowie-Dick Simulation test - Steam

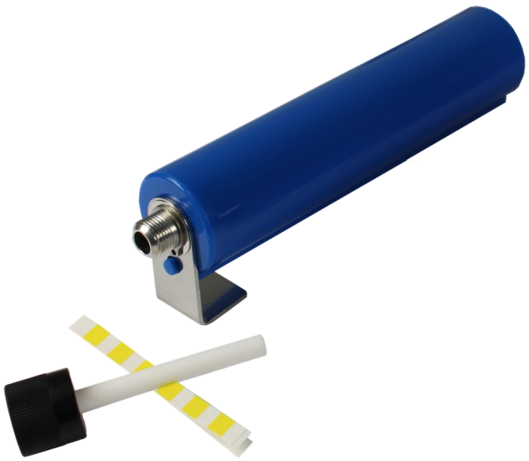
1. Chemical Indicators (steam sterilization processes)

1.1. Bowie-Dick Simulation Test (BDS-Test)

Used in vacuum steam sterilization processes checking leaks, non condensable gases (NCG) and/or insufficient air removal and to assure steam penetration. The BDS indicator strip is placed into the BDS test device and sterilized in an empty chamber at 121 °C, 15 min or 132 - 137 °C, 3 - 3.5 min (BD test program). Please refer to the GKE colour reference chart. There are three different versions available.

1.1.1. Compact-PCD®, colour: blue (EU-Version + Hollow Load Test)

Air removal and steam penetration test. European version simulating 7 kg cotton pack according to EN ISO 11140-4 and hollow load test according to EN ISO 11140-6.



Art. No.	Quantity	Product Code	Content
211-151	1	C-S-BDS-EUH-RCPCD	PCD, round
211-150	1+100	C-S-BDS-EUH-RCPCD-KIT	PCD, round, + 100 indicator strips

1.1.2. Compact-PCD®, colour: purple (EU-Version)

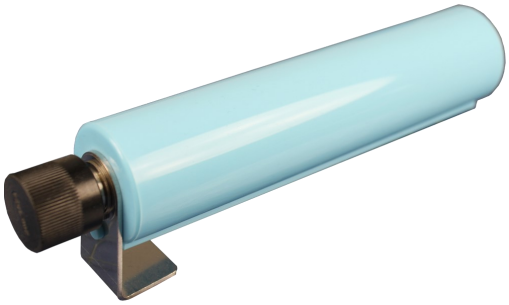
Air removal and steam penetration test. European Version simulating 7 kg cotton pack according to EN ISO 11140-4.

Art. No.	Quantity	Product Code	Content
211-121	1	C-S-BDS-EU-RCPCD	PCD, round
211-120	1+100	C-S-BDS-EU-RCPCD-KIT	PCD, round, + 100 indicator strips

Bowie-Dick Simulation test- Steam

1.1.3. Compact-PCD®, colour: light blue (US-Version)

American Bowie-Dick Simulation Test: Air removal test according to AAMI/ANSI ST79 (4 kg cotton pack) and validated with the test method described in ISO 11140-5.



Art. No.	Quantity	Product Code	Content
211-131	1	C-S-BDS-USA-RCPCD	PCD, round
211-130	1+100	C-S-BDS-USA-RCPCD-KIT	PCD, round, + 100 indicator strips

1.1.4. Refill pack indicator strips for BDS-Test

The indicator strips are equal for all versions and are included in all BDS start up kits and refill packs. Those indicator strips are used inside a GKE BDS-PCD, so this combination becomes a type 2 indicator system according to EN ISO 11140-1. Each refill pack contains 1 seal ring for exchange in the screw cap of the PCD.

Art. No.	Quantity	Product Code	Content
211-111	100	C-S-BDS-SV1	BDS indicator strips
211-112	250		
211-115	500		

Process | Batch Monitoring - Steam

1.2. Process and Batch Monitoring Systems (Hollow load test systems)

Batch Monitoring Systems (BMS) are validated according to the load configuration and are used for **routine monitoring of each batch**.

Process Monitoring Systems (PMS) are used **to check the air removal characteristics of sterilizers.** Those tests are so-called type tests that are described in the sterilizer standards (e.g. BD Test and Helix Test according to EN 285 and EN ISO 11140-6). PMS are sometimes designed to be more challenging than type tests and exceed the penetration performance in order to assure sterilization of complex loads.

Process Monitoring Systems can also be used as Batch Monitoring Systems. It is recommended to always use the PMS with the highest test requirements that has just passed in a validated process.

The indicator strip is placed into the process challenge device (PCD). The test device is sterilized together with the load. More PCDs and testsets can be found in section 5.

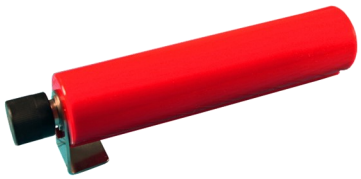
1.2.1. Compact-PCD®, colour: green, less demanding requirements than EN ISO 11140-6

Art. No.	Quantity	Product Code	Content
200-020	1	PM-SHL-RCPCD	PCD, round
211-253	1+100	C-S-PM-SHL-RCPCD-KIT	PCD, round + 100 indicator strips
200-024	1	PM-SHL-OCPCD	PCD, oval
211-254	1+100	C-S-PM-SHL-OCPCD-KIT	PCD, oval + 100 indicator strips

1.2.2. Compact-PCD®, colour: orange, Hollow Load Test according to EN ISO 11140-6

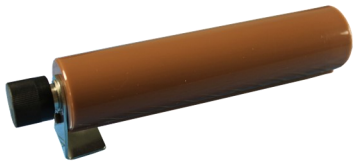
Art. No.	Quantity	Product Code	Content
200-021	1	PM-HL-RCPCD	PCD, round
211-263	1+100	C-S-PM-HL-RCPCD-KIT	PCD, round + 100 indicator strips
200-026	1	PM-HL-OCPCD	PCD, oval
211-264	1+100	C-S-PM-HL-OCPCD-KIT	PCD, oval + 100 indicator strips

1.2.3. Compact-PCD®, colour: red, higher requirements than EN ISO 11140-6



Art. No.	Quantity	Product Code	Content
200-029	1	PM-HDH-RCPCD	PCD, round

1.2.4. Compact-PCD®, colour: brown, much higher requirements than EN ISO 11140-6



Art. No.	Quantity	Product Code	Content
200-030	1	PM-VHDH-RCPCD	PCD, round

Process | Batch Monitoring - Steam

1.2.5. Load-related Batch Monitoring Systems

These test systems are validated with a test method according to DIN 58921 (medical device simulator) with typical loads by an accredited laboratory.

1.2.5.1. Ophthal-BMS with Compact-PCD®, colour: white

Art. No.	Quantity	Product Code	Content
200-091	1	BMS-Ophthal-OCPCD	PCD, oval
211-291	1+100	C-S-BMS-Ophthal-OCPCD-KIT	PCD, oval + 100 indicator strips

1.2.5.2. Dental-BMS with Compact-PCD®, colour: yellow

Art. No.	Quantity	Product Code	Content
200-081	1	BMS-Dental-OCPCD	PCD, oval
211-281	1+100	C-S-BMS-Dental-OCPCD-KIT	PCD, oval + 100 indicator strips

1.2.5.3. Tattoo-BMS with Compact-PCD®, colour: black

Art. No.	Quantity	Product Code	Content
200-071	1	BMS-Tattoo-OCPCD	PCD, oval
211-271	1+100	C-S-BMS-Tattoo-OCPCD-KIT	PCD, oval + 100 indicator strips

1.2.6. Indicator strips for steam sterilization processes

To be used in all GKE BMS/PMS process challenge devices (available in all start-up kits and refill packs). The combination of indicator strip and GKE-PCD is a Type 2 indicator system according to EN ISO 11140-1. Each refill pack contains 1 seal ring for exchange in the screw cap of the PCD.

1.2.6.1. for standard steam sterilization processes (121 °C, 15 min / 134 °C, 3 min)

Art. No.	Quantity	Product Code	Content
211-251	100	C-S-PM-SV1	Indicator strips for standard steam sterilization processes
211-252	250		
211-255	500		

1.2.6.2. for prion steam sterilization processes (134 °C, 18 min)

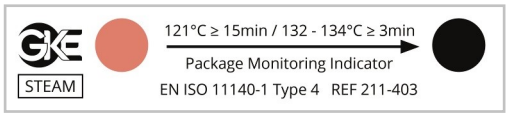
Art. No.	Quantity	Product Code	Content
211-211	100	C-S-PM-SV2	Indicator strips for prion steam sterilization processes
211-212	250		
211-215	500		

Package Monitoring - Steam

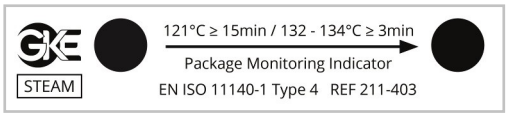
1.3. Self-adhesive Package Monitoring Indicators for steam sterilization processes

The indicators are used inside packs or containers to monitor all relevant variables of steam sterilization processes. These indicators should only be used if solid instruments and porous goods (no hollow devices) are sterilized. Package monitoring indicators only provide sterility information at the position inside the chamber where they are located. If only cross contamination on surfaces of the instruments should be prevented, the instruments are sterilized without being packaged. In special combination autoclaves that clean, lubricate and sterilize dental instruments, the indicator is also placed unpacked into the indicator holder inside the chamber. All indicators fulfil the requirements according to EN ISO 11140-1 Type 4, 5 or 6 and test the critical variables (temperature, time and condensate/water) with different defined pass/fail windows. They are self-adhesive and can be used for documentation.

1.3.1. Type 4 Indicators (wide pass/fail window)



before sterilization



after sterilization

Art. No.	Quantity	Product Code	Dimension	Content
211-403	3,200	C-S-P-4-SV1	65 x 14 mm	Type 4 indicators, self-adhesive

1.3.2. Type 5 integrating indicators without printing possibility (standard pass/fail window)

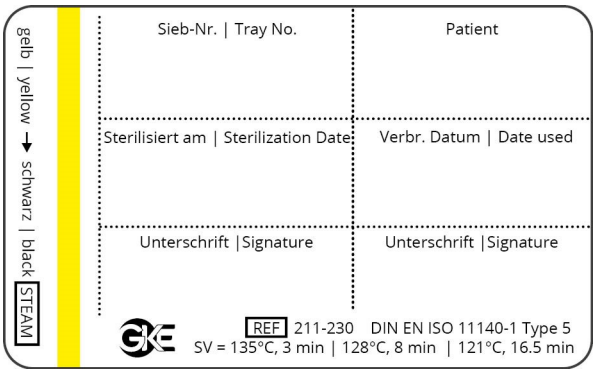
before sterilization

after sterilization

Art. No.	Quantity	Product Code	Dimension	Content
211-221	100	C-S-P-5-SV1	14 x 65 mm	Type 5 indicators, self-adhesive
211-224	400			
211-226	3,200			

Package Monitoring - Steam

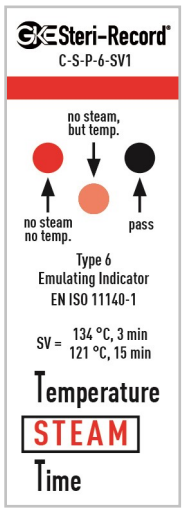
1.3.3. Type 5 integrating indicators with printing possibility, self-adhesive (standard pass/fail window)



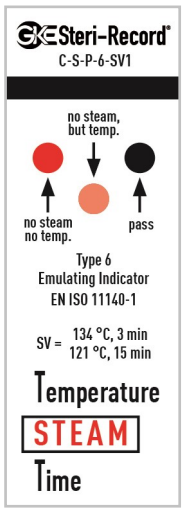
Art. No.	Quantity	Product Code	Content/Dimensions
211-230	1,000	C-S-P-5-78x48-SA-SV1	Labels (78 x 48 mm) on roll with 3“ core

1.3.4. Type 6 emulating indicators (small pass/fail window)

for standard steam sterilization processes
SV = 121 °C, 15 min / 134 °C, 3 min

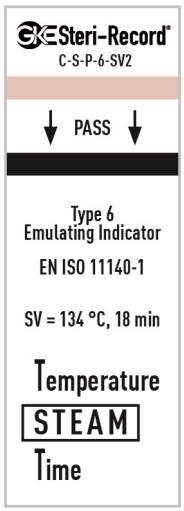


before sterilization



after sterilization

for prion steam sterilization processes
SV = 134 °C, 18 min



before sterilization

after sterilization

Art. No.	Quantity	Product Code	Dimension	Application
211-243	250	C-S-P-6-SV1	23 x 66 mm	for standard steam sterilization processes
211-242	500			
211-241	2,000			
211-240	250	C-S-P-6-SV2	23 x 66 mm	for prion steam sterilization processes
211-238	2,000			

Process Indicators - Steam

1.4. Process indicators for steam sterilization processes

Process indicators according to EN ISO 11140-1 Type 1 are adhered on each sterilization package on plastic, paper, (non-)woven and change their colour during sterilization to provide logistical information if the pack has passed a sterilization process or not. Process indicators do not inform about the quality of the sterilization process.

There are single self-adhesive labels to be adhered or slipped on containers and double self-adhesive labels to be adhered on packs. They can be removed off the second layer and adhered again for documentation.
Plastic inserts to reduce the core diameter to 2“ or 1“ are available free of charge.

Art. No.	Product Code	Description	Quantity
000-332	Reducing insert	3“ to 2“	2
000-315		3“ to 1.5“	
000-331		3“ to 1“	
000-221		2“ to 1“	

If larger amounts of labels are ordered, labels with other dimensions, different number of labels per roll and other core diameter can be produced.

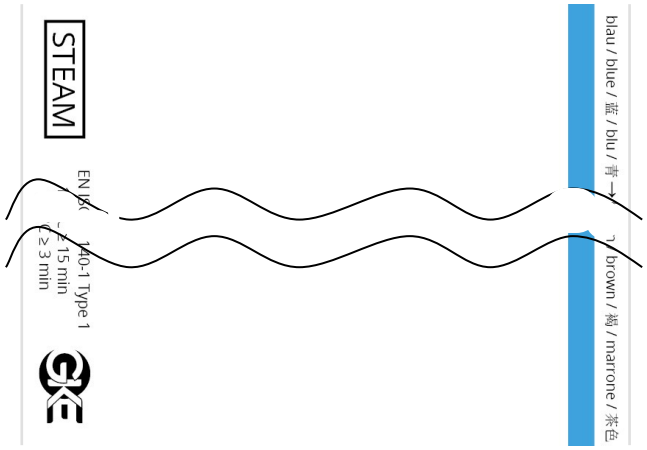
All GKE process indicators for steam sterilization processes change their colour from blue to brown/black as shown:

before sterilization after sterilization

1.4.1. Double self-adhesive 3-layer labels, on roll

They can be used for documentation due to extra layer.

1.4.1.1. Endless labels to be used in printers with cutting device

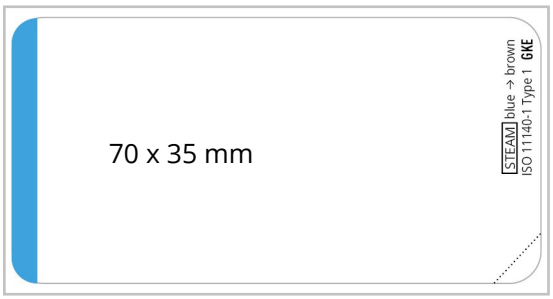


Art. No.	Product Code	Width	Length	Outside roll diameter	Roll core	Adhesion
211-390	C-S-L-1-70-DA	7 cm	70 m	15.7 cm	3“	Standard
211-394	C-S-L-1-80-DA		80 m	15.4 cm	2“	
211-490	C-S-L-1-70-DA-IA		70 m	15.7 cm	3“	Strong

Process Indicators - Steam

1.4.1.2. Labels of 58, 70 and 78 mm width, for non-woven materials, each separated from each other with perforation

Corner Split



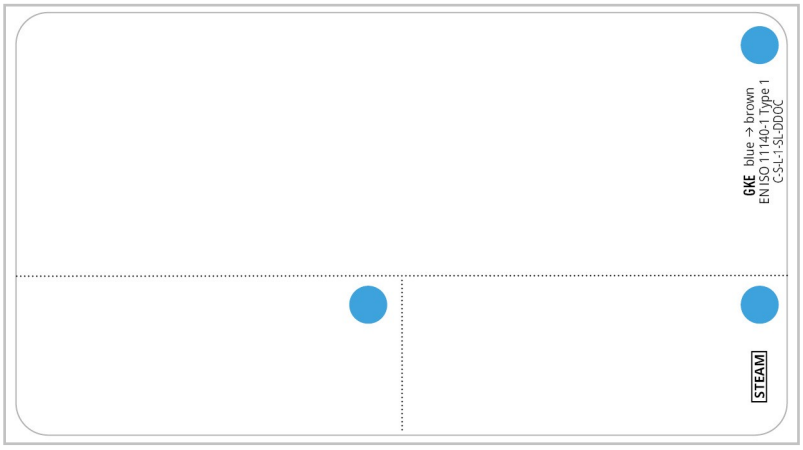
Corner Split

Corner Split

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core	Adhesion
211-342	C-S-L-1-60x40-SC-DA	800	58 x 35 mm	12 cm	3“	Standard
211-345	C-S-L-1-60x40-SU-DA (Split: bottom)			10.6 cm	2“	
211-282	C-S-L-1-60x40-SC-DA	1,000		11 cm	1.5“	
211-338	C-S-L-1-70x40-SC-DA	1,000	70 x 35 mm	11 cm	1.5“	Standard
211-349	C-S-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3“	
211-449	C-S-L-1-80x40-SC-DA -IA					Strong
211-448		1,500		15 cm		

Process Indicators - Steam

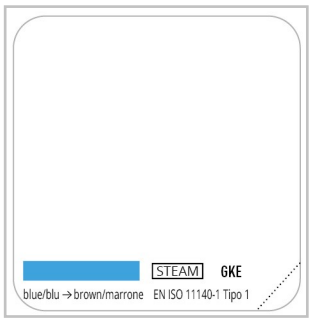
1.4.1.3. Labels 102 x 56 mm, for the Getinge documentation system



horizontal and vertical splits, separation in 3 segments

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core	Adhesion
211-367	C-S-L-1-SL-DDOC	800	102 x 56 mm	11.6 cm	1“	Standard
211-369				12 cm	1.5“	
211-370				13.6 cm	3“	
211-469	C-S-L-1-SL-DDOC-IA			12 cm	1.5“	Strong

1.4.1.4. Labels 38 x 39 mm, for non-woven materials



Corner Split

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
211-377	C-S-L-1-38x39-SC-DA	700	38 x 39 mm	10.5 cm	2“

Process Indicators - Steam

1.4.2. Single self-adhesive 2-layer labels

1.4.2.1. Labels 58 x 35 mm and 78 x 35 mm, each separated from each other with perforation, to be directly adhered on containers

The labels are made of plastic material, to be directly adhered on containers and can be removed without leaving any residues and documented.

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
211-142	C-S-L-1-60x40-SA-R	1,000	58 x 35 mm	11 cm	3“
211-149	C-S-L-1-80x40-SA-R		78 x 35 mm		1“

1.4.2.2. Container label 38 x 60 mm for manual labelling or with printer

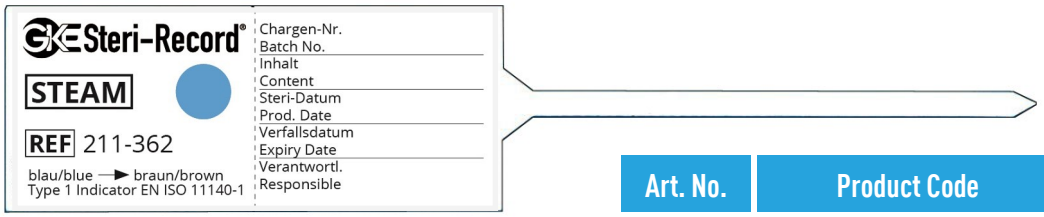
The single self-adhesive container labels are put into packs, pouches or slipped on containers which have to be sterilized. After sterilization they are adhered onto the patient documentation sheet. It can be labelled with expiry date or a 3-line documentation label can be adhered onto the container label. Colour change see 1.4.

Art. No.	Product Code	Labels/roll	Dimension	Outside roll diameter	Roll core
211-341	C-S-L-1-CL-40x60-SA	1,000	60 x 38 mm	14 cm	3“

Process Indicators - Steam

1.4.3. Container seal

The self-adhesive container seal seals the container and contains a process indicator. It can be manually labelled or labelled with a 3-line documentation label (see 6.).



Art. No.	Product Code	Quantity	Dimension
211-362	C-S-L-1-CS	1,008	70 x 29 mm 75 mm pin

1.4.5. Autoclave tape

The autoclave tape with process indicator is available on roll with 50 m length and 19 mm width and is used to seal packs.

Art. No.	Product Code	Quantity	Content	Colour Change
211-351	C-S-L-1-AT-IA	12	Autoclave tape rolls	green to black
211-352		48		
211-354	C-S-L-1-AT	10		yellow to black
211-355		50		

2. Chemical Indicators (ethylene oxide sterilization processes)

2.1. Process Challenge Device (PCD)

to monitor the efficiency of EO gas in each batch. The indicator strip is placed into the PCD which contains a stainless steel tube of 4.5 m lengths with an inner diameter of 4.5 mm (5 mm outside). The test device is sterilized together with the load. Other PCDs can be found in 5.1.

Art. No.	Product Code	Quantity	Content
200-028	C-E-PM-HPCD	1	Stainless steel Helix-PCD according to EN 1422:2009 (Line/Pickerell)

Indicators for EO Processes

2.2. Indicator strips for batch and process monitoring

to be used in all GKE BMS/PMS process challenge devices. The combination of indicator strip and GKE-PCD is a Type 2 indicator system according to EN ISO 11140-1.

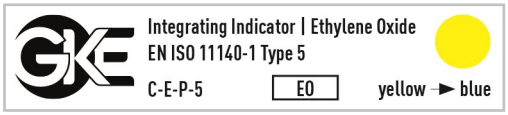
before sterilization

after sterilization

Art. No.	Product Code	Quantity	Content
212-202	C-E-PM	250	Indicator strips (colour change: blue to green)
212-201			Indicator strips (colour change: yellow to blue)

2.3. Self-adhesive Type 5 indicators according to EN ISO 11140-1

The indicators are placed into packages or containers to monitor the relevant variables of sterilization processes. Those indicators should only be used if solid instruments or porous goods (no hollow devices!) are sterilized. Package monitoring indicators only provide sterility information at the position inside the chamber where they are located



Art. No.	Product Code	Quantity	Dimension	Content
212-224	C-E-P-5	400	65 x 14 mm	Integrating Indicator Type 5
212-226		3,200		

2.4. Indicator tape

The indicator tape with ethylene oxide process indicator is available on roll with 50 m length and 19 mm width and is used to seal packs.

Art. No.	Product Code	Quantity	Application
212-354	C-E-L-1-AT	10	to seal packs
212-355		50	

2.5. Double self-adhesive labels

Art.-No.	Product Code	Labels/Roll	Dimension	Outside roll diameter	Roll core
212-349	C-E-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3“

INDICATORS FOR LTSF PROCESSES

3. Chemical Indicators for formaldehyde sterilization processes

3.1. Process Challenge Device (PCD)

to be used in Low Temperature Steam Formaldehyde (LTSF) sterilizers to test sufficient formaldehyde penetration. The indicator strip is placed into the PCD. The test device is sterilized together with the load. More PCDs can be found in 5.

Art. No.	Product Code	Quantity	Content
200-150	PM-HPCD-2-150	1	Helix-PCD according to EN ISO 11140-6
200-218	PM-RCPCD-8		Compact-PCD according to EN ISO 11140-6

3.2. Indicator strips for batch and process monitoring

to be used in all GKE BMS/PMS process challenge devices. The combination of indicator strip and GKE-PCD is a Type 2 indicator system according to EN ISO 11140-1.

before sterilization

after sterilization

Art. No.	Product Code	Quantity	Content
213-202	C-F-PM	250	Indicator strips

3.3. Self-adhesive Type 4 package monitoring indicators according to EN ISO 11140-1

The indicators are placed into packages or containers to monitor the relevant variables of sterilization processes. Those indicators should only be used if solid instruments or porous goods (no hollow devices!) are sterilized. Package monitoring indicators only provide sterility information at the position inside the chamber where they are located. After sterilization they can be adhered for documentation. The indicators are self-adhesive.

before sterilization

after sterilization

Art. No.	Product Code	Quantity	Dimension	Content
213-221	C-F-P	400	65 x 14 mm	Package Monitoring Indicators

INDICATORS FOR H_2O_2 PROCESSES

4. Chemical Indicators for hydrogen peroxide (H_2O_2)/plasma sterilization processes

All indicators and labels for hydrogen peroxide (H_2O_2) sterilization processes have a plastic foil carrier since paper must not be used in those processes. They can also be used for disinfection.

4.1. Process Challenge Devices (PCD) and Testset

The indicator strip is placed into the PCD. The test device is sterilized together with the load. The penetration characteristics of all hydrogen peroxide/plasma sterilization processes into hollow devices are less compared to steam sterilization processes. For this reason less sensitive Helix-PCDs with shorter tube lengths and larger tube diameter have been developed to check the limits of hydrogen peroxide sterilization processes. In contrast to steam sterilization processes tubes with small diameters are more difficult to penetrate than with large diameters. More PCDs in Compact-PCD design can be found in 5.1.

Art. No.	Product Code	Tube		Quantity
		Diameter [mm]	Length [cm]	
200-016	PM-HPCD-TS-10	Testset with 10 PCDs		10
200-525	PM-HPCD-5-25	5	25	1
200-550	PM-HPCD-5-50	5	50	
200-575	PM-HPCD-5-75	5	75	
200-510	PM-HPCD-5-100	5	100	
200-425	PM-HPCD-4-25	4	25	
200-450	PM-HPCD-4-50	4	50	
200-475	PM-HPCD-4-75	4	75	
200-325	PM-HPCD-3-25	3	25	
200-350	PM-HPCD-3-50	3	50	
200-025	PM-HPCD-2-25	2	25	

4.2. Indicator strips for batch and process monitoring

to be used in all GKE BMS/PMS process challenge devices. The combination of indicator strip and GKE-PCD is a Type 2 indicator system according to EN ISO 11140-1.

before sterilization

after sterilization

Art. No.	Product Code	Quantity	Content
214-201	C-V-PM	250	Indicator strips (colour change: red to yellow)

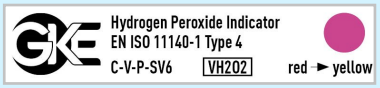
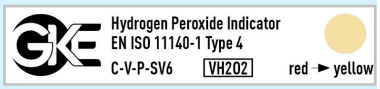
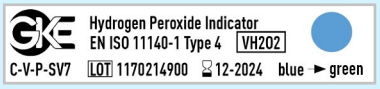
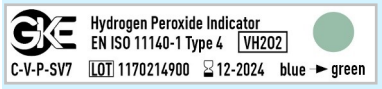
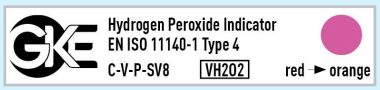
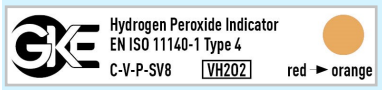
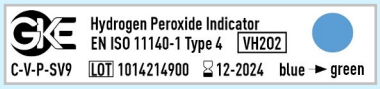
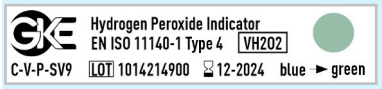
Indicators for H_2O_2 Processes

4.3. Self-adhesive Type 4 package monitoring indicators (65 x 14 mm) according to EN ISO 11140-1 for use in VHPO sterilizers and in H_2O_2 disinfection processes

The indicators are placed into packages or containers to monitor the relevant variables of sterilization processes. Those indicators should only be used if solid instruments or porous goods (no hollow devices!) are sterilized. Package monitoring indicators only provide sterility information at the position inside the chamber where they are located. After sterilization they can be adhered for documentation.

Alternatively those indicators can also be used to monitor disinfection processes (e.g. in rooms or isolators).

The indicators are available with different stated values, different colour changes and increasing sensitivities.

Level	Art.-No.	Quantity	SV at 50° gas phase	Before sterilization/ room disinfection	After sterilization/ room disinfection
1	**214-250** **214-251** **214-253**	160 400 3.200	2,6 mg H2O2/L, 2 min		
2	**214-241** **214-243**	400 3.200	2,6 mg H2O2/L, 8 min		
3	**214-260** **214-261**	160 400	2,6 mg H2O2/L, 15 min		
4	**214-221** **214-223**	400 3.200	3,8 mg H2O2/L, 20 min		

4.4. Indicator tape

The indicator tape with hydrogen peroxide process indicator is available on roll with 50 m length and 19 mm width and is used to seal packs. It can be replaced by packing tape and H2O2 documentation labels (see 4.5).

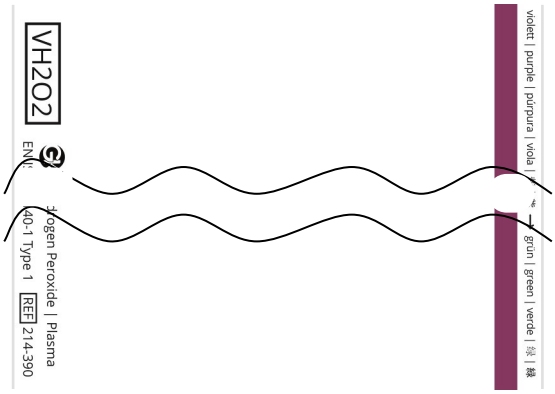
Art. No.	Product Code	Quantity	Application
214-354	C-V-L-1-AT	2	to seal packs

Indicators for H_2O_2 Processes

4.5. Double self-adhesive labels to be used in printers

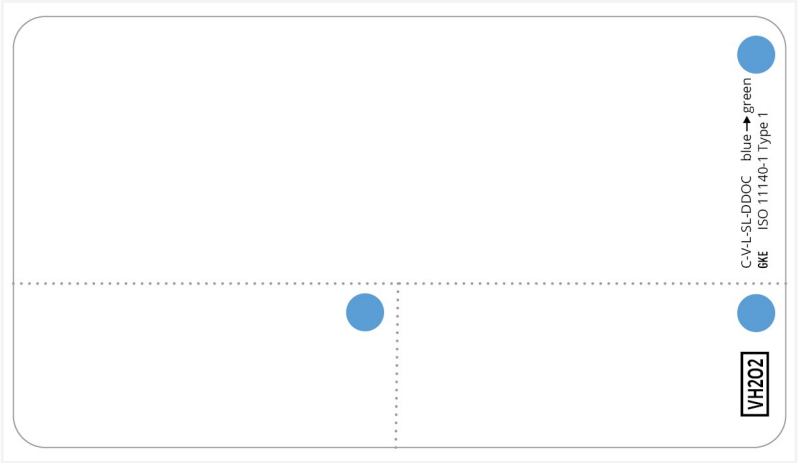
The labels with process indicator according to EN ISO 11140-1 type 1 are used in printers with and without cutting device. After the information is printed the label can be adhered on sterilization packs or pouches and after opening them for medical treatment they can be transferred to the patient documentation. The chemical indicator provides logistic information if the package has passed a sterilization process.

4.5.1. Endless label with 7 cm width to be used in printers with cutting device



Art. No.	Product Code	Width	Length	Outside roll diameter	Roll core
214-390	C-V-L-1-60-DA	7 cm	60 m	14.7 cm	3“

4.5.2. Different single labels



horizontal and vertical splits,
separation in 3 segments

Art. No.	Product Code	Labels/ roll	Dimension	Outside roll diameter	Roll core
214-369	C-V-L-1-SL-DDOC	800	102 x 56 mm	12 cm	1,5“
214-349	C-V-L-1-80x40-SC-DA	800	78 x 35 mm	12 cm	3“

5. Testsets and PCDs

Testsets are used to test the penetration limits of the sterilant in different sterilization processes. The testsets contain PCDs with different penetration characteristics. All PCDs can be used with GKE biological or chemical indicators, available for steam, ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes. Please order the corresponding biological or chemical indicator strips, a PCD or testset, see 1.2.6 (steam), 2.2 (ethylene oxide), 3.2 (formaldehyde) or 4.2 (hydrogen peroxide/plasma).

5.1. Compact-PCD-Testset, consisting of 10 Compact-PCDs, grey

To test steam, ethylene oxide and formaldehyde sterilization processes.

Art. No.	Product Code	Comparable with PCD	Quantity
200-211	PM-RCPCD-1	200-071 (Tattoo)	1
200-212	PM-RCPCD-2		
200-213	PM-RCPCD-3	200-081 (Dental)	
200-214	PM-RCPCD-4		
200-215	PM-RCPCD-5		
200-216	PM-RCPCD-6	200-091 (Ophthal)	
200-217	PM-RCPCD-7	200-020 (green)	
200-218	PM-RCPCD-8	200-021 (orange)	
200-219	PM-RCPCD-9	200-029 (red)	
200-220	PM-RCPCD-10	200-030 (brown)	
200-210	PM-RCPCD-TS	Testset with 10 CPCDs	10

5.2. Helix-Testsets

To test steam, formaldehyde and hydrogen peroxide sterilization processes.

Art. No.	Product Code	Tube		Quantity
		Diameter [mm]	Length [cm]	
200-025	PM-HPCD-2-25	2	25	1
200-050	PM-HPCD-2-50	2	50	
200-075	PM-HPCD-2-75	2	75	
200-100	PM-HPCD-2-100	2	100	
200-150	PM-HPCD-2-150	2	150	
200-013	PM-HPCD-TS-5	Testset with above PCD		5

Art. No.	Product Code	Tube		Quantity
		Diameter [mm]	Length [cm]	
200-150	PM-HPCD-2-150	2	150	1
200-302	PM-HPCD-2-300	2	300	
200-452	PM-HPCD-2-450	2	450	
200-153	PM-HPCD-3-150	3	150	
200-303	PM-HPCD-3-300	3	300	
200-154	PM-HPCD-4-150	4	150	
200-304	PM-HPCD-4-300	4	300	
200-510	PM-HPCD-5-100	5	100	
200-205	PM-HPCD-5-200	5	200	
200-305	PM-HPCD-5-300	5	300	
200-405	PM-HPCD-5-400	5	400	
200-505	PM-HPCD-5-500	5	500	
200-605	PM-HPCD-5-600	5	600	
200-017	PM-HPCD-TS-13	Testset with above PCD		13

6. Documentation System

6.1. Hand labelling devices

The GKE Steri-Record® documentation system is used for batch- and patient-related traceability after sterilization of medical devices.

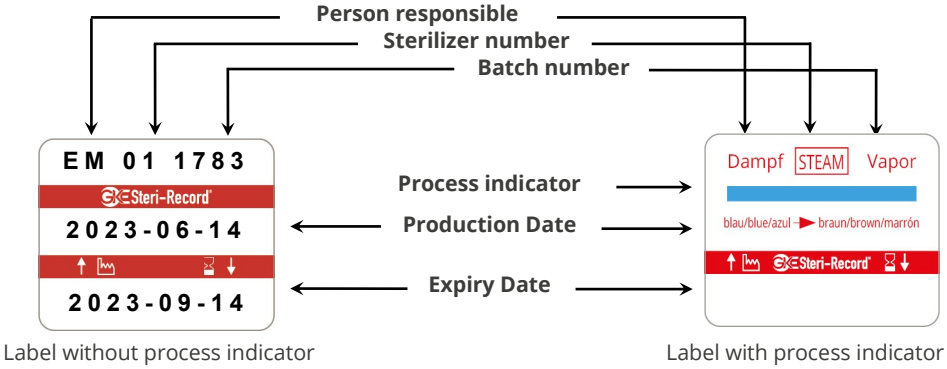
By using a GKE labelling device a label of the same content including production and expiry date, batch number and responsible person is adhered on each pack and on the documentation sheet. After opening the sterile pack in the operation room the label can be removed from the package and adhered into the patient file.Thus all information provided on each pack can be traced back from the patient to the processing and approval.

The labels are available in different colours, optionally with or without indicator.

GKE offers two versions of hand labelling devices:

Art. No.	Product Code	1. Printing line	2. + 3. Printing line
240-820	D-G-NL	3 alpha-numeric and 9 numeric digits	12 numeric digits
240-830	D-G-AL	12 alpha-numeric digits	
240-892	Ink roll	for all GKE hand labelling devices	

The following example shows two labels (with and without process indicator). A label without indicator was labeled using a labeller:



Label without process indicator

Label with process indicator

Documentation System

6.2. Double self-adhesive 3-line labels with advanced adhesion properties

The labels consist of a 3 layer material and can be directly adhered on packages or on other labels, e.g. container labels. Before the pack is opened in the operation theatre the double self-adhesive label can be taken off and adhered onto the patient documentation sheet. All indicators are tested according to EN ISO 11140-1 type 1 and come with a conformity declaration.

The labels are available in four different colours without (6.2.1) or with (6.2.2) process indicator for steam sterilization processes. The labels are also available with process indicator for ethylene oxide, formaldehyde and hydrogen peroxide sterilization processes (6.2.3). Each pack contains 2, 4 or 12 rolls with 750 labels and an **ink roll** for the hand labelling device.

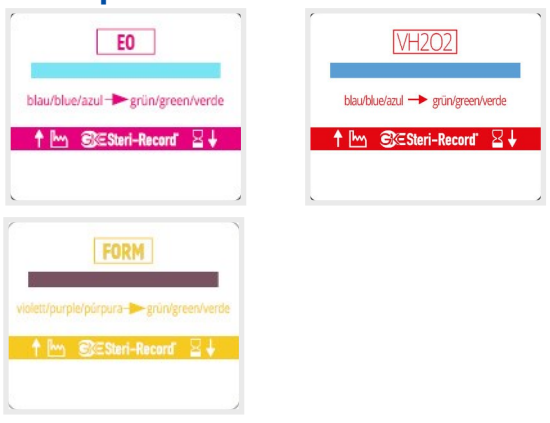
6.2.1. without indicator

Art. No.	Product Code	Colour	Quantity
240-853	D-L-DA-R	red	4
240-861	D-L-DA-G	green	12
240-862	D-L-DA-B	blue	
240-863	D-L-DA-R	red	
240-864	D-L-DA-Y	yellow	

6.2.2. with process indicator for steam sterilization processes

Art. No.	Product Code	Colour	Quantity
240-883	C-S-L-1-DA-R	red	4
240-871	C-S-L-1-DA-G	green	12
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	

6.2.3. with process indicator for different sterilization processes



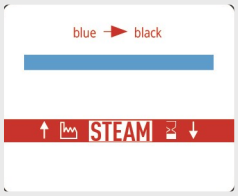
Art. No.	Product Code	Colour	Quantity	Process
242-885	C-E-L-1-DA-P	pink	2	EO
242-875			12	
243-884	C-F-L-1-DA-Y	yellow	2	FORM
243-874			12	
244-883	C-V-L-1-DA-R	red	2	H_2O_2
244-873			12	

Documentation System

6.3. Double self-adhesive 3-line ECO labels

The labels consist of a 3-layer material with standard adhesion properties and are available without and with process indicator for steam or ethylene oxide. No conformity declaration and no test report available. Each pack contains 12 rolls with 750 labels, NO ink roll.

without indicator



with steam process indicator

with ethylene oxide process indicator

Art. No.	Product Code	Colour	Quantity	Process
000-863	D-L-DA-R-ECO	red	12	all (without indicator)
000-873	C-S-L-1-DA-R-ECO			Steam
000-875	C-E-L-1-DA-P-ECO	pink		EO

6.4. Single self-adhesive 2-line labels

The labels consist of a 2 layer material and can be adhered.

The labels are available without (6.4.1) or with (6.4.2) process indicator for steam sterilization processes. Each pack contains 12 rolls with 1,000 labels, NO ink roll.

6.4.1. without indicator

Art. No.	Product Code	Colour	Quantity	Process
230-864	D-L-SA-Y	yellow	12	all

6.4.2. with process indicator for steam sterilization processes

Art. No.	Product Code	Colour	Quantity	Process
230-872	C-S-L-1-SA-B	blue	12	steam

7. Seal-Test for routine control of sealing seams

The GKE seal-test indicator is used for daily routine control of sealing seams and for the operational qualification of different sealing machines in accordance with EN ISO 11607-2.

7.1. for rotary sealing machines (173 x 76.2 mm)

Art. No.	Product Code	Content	Quantity
200-311	SEAL-TEST	Seal indicator to check paper/ plastic film pouches	100
200-312			250
200-321	HDPE-SEAL-TEST	Seal indicator to check Tyvek® pouches	100

7.2. for bar sealing machines (250 x 76.2 mm)

Art. No.	Product Code	Content	Quantity
200-331	BAR-SEAL-TEST	Seal indicator to check paper/ plastic film pouches	100

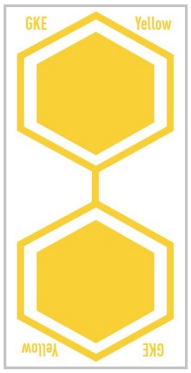
8. Cleaning process monitoring indicators (CPI) and accessories

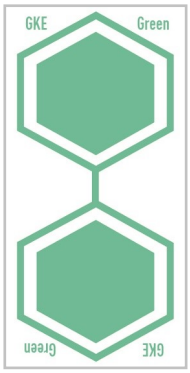
Self-adhesive CPI are used in washer-disinfectors (WD) (8.1), in ultrasonic cleaning baths (8.2), in bedpan washers (8.3) and in textile washing machines (8.4). The indicator that has been washed off at the latest, should basically be used to check the cleaning process. There are five different indicators available with increasing wash-off characteristics. The suitable indicator can be selected during a test run. If the WD is equipped with a glass door, the indicators can be placed so that the wash-off characteristics are visible through the window and the indicator that has been washed off at the latest can be determined. In WD without glass doors the indicator that has just been fully washed off should be selected for process monitoring.

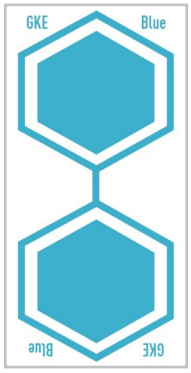
8.1. for washer disinfectors (WD)

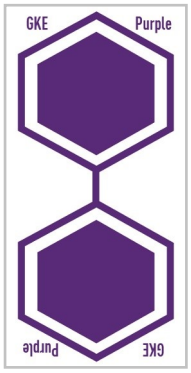
The CPI are available on sheets with 16 double-sided indicators. The indicator is placed in a holder or inside a Hollow Flow PCD.

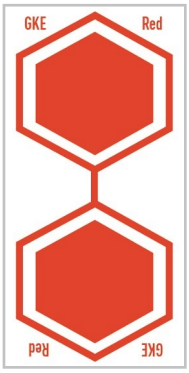
8.1.1. Cleaning process monitoring indicators, indicator pair

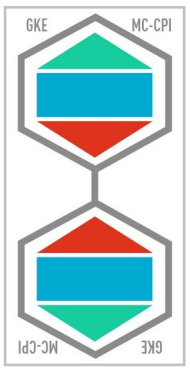












* MC

Art. No.	Product Code	Quantity
810-101	W-CPI-Y (Cleaning process indicators, yellow)	160
810-102		480
810-103		960
810-201	W-CPI-G (Cleaning process indicators, green)	160
810-202		480
810-203		960
810-301	W-CPI-B (Cleaning process indicators, blue)	160
810-302		480
810-303		960
810-351	W-CPI-P (Cleaning process indicators, purple)	160
810-352		480
810-353		960
810-401	W-CPI-R (Cleaning process indicators, red)	160
810-402		480
810-403		960
810-901	W-MC-CPI (Cleaning process indicators, green, blue, red)	160
810-902		480
810-903		960

* combines the wash-off characteristics of above mentioned Indicators (green, blue, red) on one indicator

8.1.2. Holder and Hollow Flow PCD for cleaning process monitoring indicators

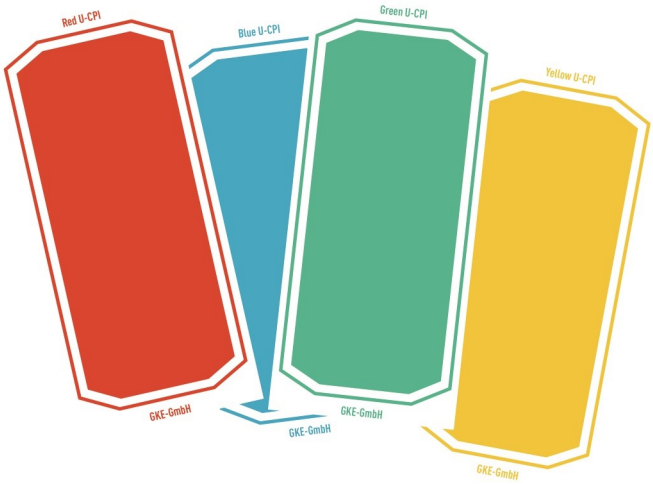
Art. No.	Product Code	Content	Quantity
800-102	W-PHO	Plastic holder	10
800-111	W-HF-PCD	Hollow Flow PCD	1

Cleaning Process Monitoring

8.2. for ultrasonic cleaning baths

Self-adhesive cleaning process monitoring indicators to test ultrasonic cleaning baths, on card with 4 indicators each. The indicators are placed horizontally or vertically in the clip holder (see 8.2.2) and put in the liquid volume to check the cleaning efficacy inside the baths.

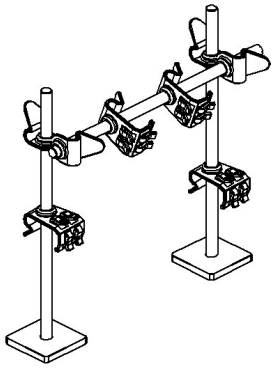
8.2.1. Ultrasonic cleaning process monitoring indicators



Art. No.	Product Code	Quantity
810-111	W-U-CPI-Y (Ultrasonic cleaning process indicators: yellow)	40
810-112		120
810-211	W-U-CPI-G (Ultrasonic cleaning process indicators: green)	40
810-212		120
810-311	W-U-CPI-B (Ultrasonic cleaning process indicators: blue)	40
810-312		120
810-411	W-U-CPI-R (Ultrasonic cleaning process indicators: red)	40
810-412		120

8.2.2. Holder for ultrasonic cleaning test sheets

Holder consisting of a bottom plate and a stainless steel bar (available in 3 different lengths) with cross connector and two height adjustable clips to fix the indicator horizontally and/or vertically inside the basin volume. Two holders can be connected by using a stainless steel bar and the cross connectors.



Art. No.	Product Code	Content	Quantity
800-115	W-U-HO-7	Holder with 7 cm stainless steel bar	1
800-116	W-U-HO-20	Holder with 20 cm stainless steel bar	
800-117	W-U-HO-40	Holder with 40 cm stainless steel bar	

Cleaning Process Monitoring

8.3. for bedpan washers

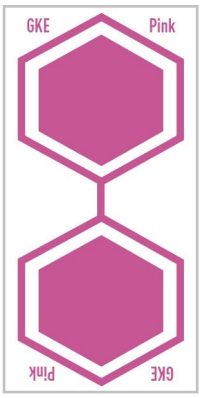
Cleaning process indicator to monitor the cleaning efficacy in bedpan washers. The indicator can be directly adhered onto the test position.

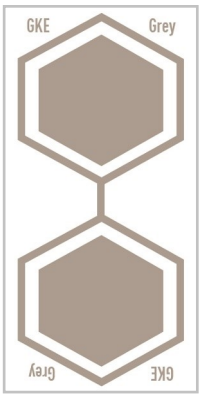
Art. No.	Product Code	Quantity double-sided indicators	Quantity single indicators
810-000	W-BP-CPI-O	64	128
810-001		160	320

8.4. for washing machines (laundry)

Cleaning process indicators are used for validation and monitoring of cleaning processes in washing machines (laundry). The indicator is placed into a Laundry-Check ball and the ball is placed into the washing drum together with the load. Indicators with stronger washing characteristics are generally used for textile cleaning monitoring, as the detergents used achieve a higher cleaning effect.

8.4.1. Cleaning process monitoring indicators

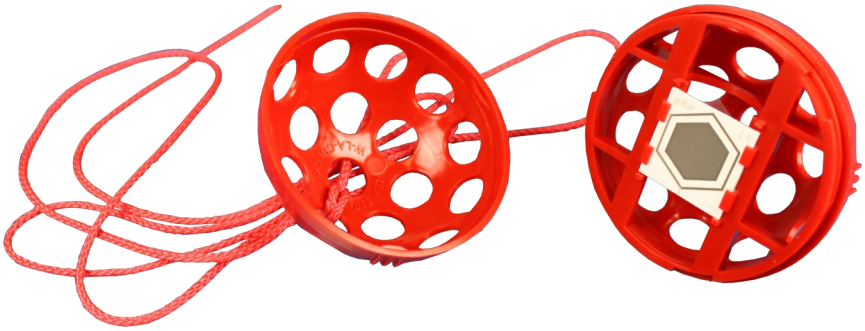




Art. No.	Product Code	Quantity
810-501	W-WA-L5 (Cleaning process indicators, pink)	160
810-601	W-WA-L6 (Cleaning process indicators, grey)	160

8.4.2. Laundry-Check Ball

The Laundry-Check Ball can be opened by unscrewing two parts. The indicator can be inserted in a holder inside the ball. Both parts are closed and put into the drum together with the laundry (load). A red cord is attached to the ball which makes it easier to find the ball in the washing drum after the process.



Art. No.	Product Code	Quantity
800-130	W-LA-CHECK	1

710-002 EN V50

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