

QUALITY MONITORING & ASSURANCE

Process monitoring and documentation have grown in importance in the field of medical device reprocessing over the past years which, in turn, has led to a significant increase in quality. The use of batch controls and random tests is common practice today and helps proper processing.

Routine controls in between annual maintenance and validation cycles provide consistent procedures and help to guarantee compliance with the applicable guidelines and standards. The Key Surgical product portfolio in this segment is growing continuously to enable you to maintain high quality standards.

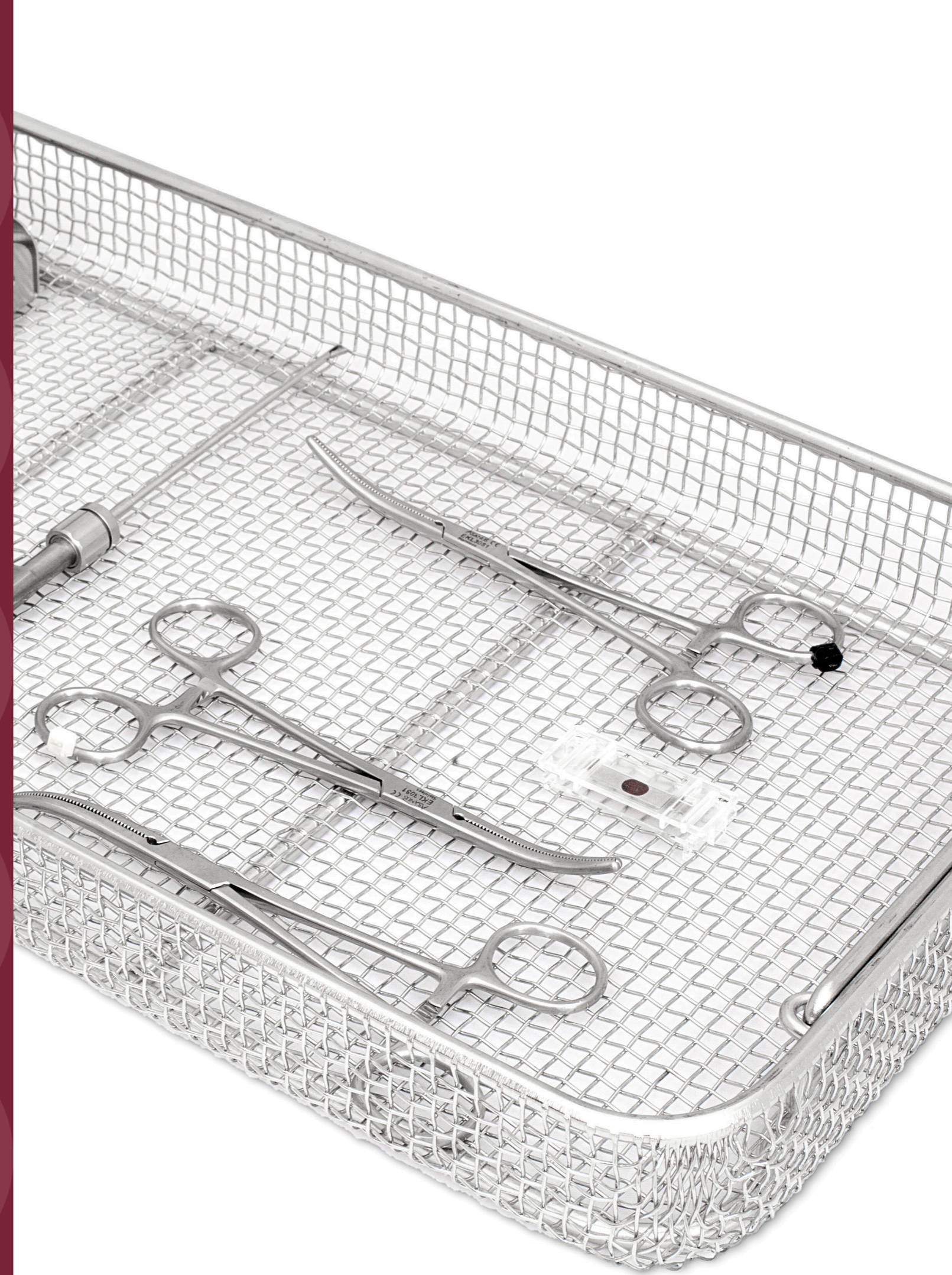
- Indicators for standard instrument and endoscope washer-disinfectors, and ultrasonic baths to check the cleaning efficacy of the cycles
- Ink-based seam seal integrity tests or color analysis with indicator strips
- Hollow load process challenge tests for routine monitoring – reusable and single use options
- Routine and batch control systems for long-term use
- Batch controls for all widely used sterilization methods such as steam, low temperature (EO, FO, H₂O₂)
- Bio-indicators for routine checks and microbiological validation of most sterilization/ disinfection procedures
- Other quality controls such as disinfection indicators, indicator dots, counting strips, control/insertion cards, sterilization protocols and documentation pads
- Test materials for quality control of medical instruments (functional capacity, cleaning outcome, information on diameter, length and weight) and for workplace optimization

Cleaning Indicators

Bowie-Dick Tests

Sterilization Monitoring

Monitoring Equipment



Unless otherwise stated, our products are not made with natural rubber latex.

Quality Monitoring & Assurance - Cleaning & Disinfection Monitoring Blood-Based Test

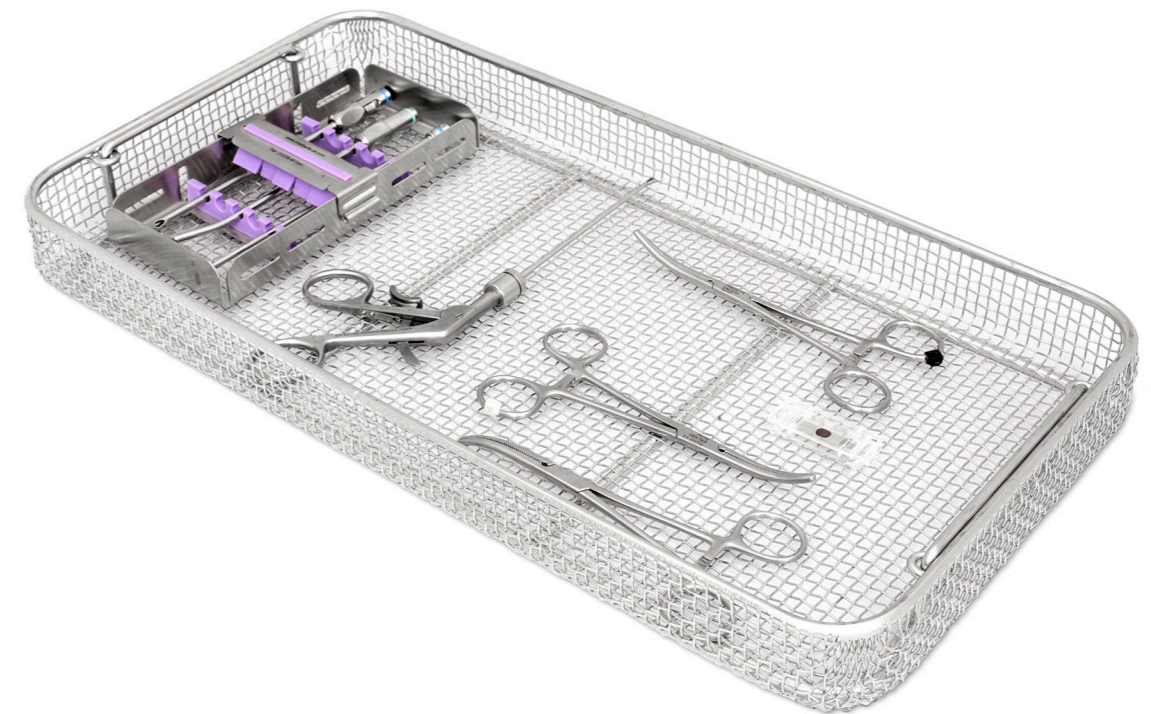
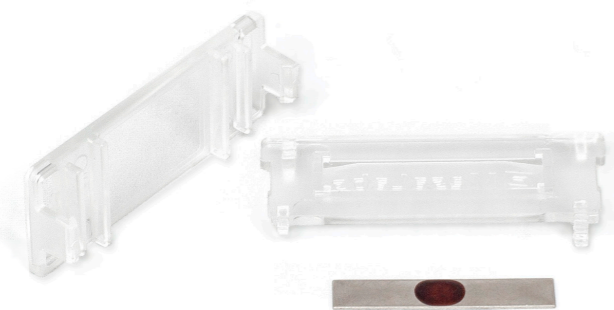
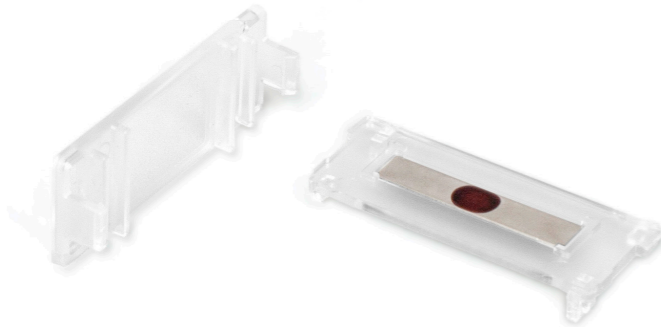
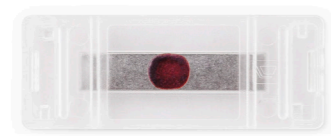
Cleaning is the first and most important step in the reprocessing cycle so it must be checked with appropriate care. Cleaning indicators and monitoring systems are used to verify cleaning performance. They are used to simulate soiled surface structure, joints, cavities and complex lumens, and challenge the efficacy of the cleaning cycle in a washer-disinfectors (WD). Results are assessed based on the presence or absence of soil in the indicator after the cleaning cycle.

A T-EZ PRO™

The T-EZ Pro "All in One" contains a sheep blood compound that correlates to human blood. It is easy to use: just remove the T-EZ Pro from its package and attach it directly to the sieve tray. Thanks to the transparency of the plastic, there is no need to remove the indicator strip from its PCD for interpretation. However, it is possible to open the test body and archive the indicator for documentation purposes.

REF	Description	Suitable to	Qty
EZ-015-100	T-EZ Pro cleaning indicator	washer-disinfectors	15 pcs

A



Quality Monitoring & Assurance - Cleaning & Disinfection Monitoring Blood-Based Test

CLEANING INDICATORS AND TEST BODIES

Cleaning indicators and test bodies for the verification of washer-disinfectors cleaning cycle. Indicators consist of a blood compound and a test body to meet EN 15883.

REF	Description	Machine type	Qty
A 08010	MIS test indicator for checking the cleaning effect	WD	1 pcs
B 08032	kit to control the cleaning effect of washer-disinfectors and ultrasonic baths consists on: 50x indicators Simicon RI (V3502080) 1x test body for standard instruments, yellow (REF 08033) 1x test model for simulating narrow gaps, blue (REF 08034) 1x test model MIS instruments	WD	1 Set
C 08009	stainless steel test body for washer disinfecter - standard instruments format: \varnothing 2.0mm x 2m	WD	1 pcs
D 08083	test body made of stainless steel, for testing the performance of washer-disinfectors, for reprocessing of flexible endoscopes according to ISO 15883 with the cleaning indicator. SIMICON-RI or bio indicator SIMICON WD-EF format: \varnothing 1.0 mm x 2 m	WD-E	1 pcs
E 08084	test body made of plastic, for testing the performance of washer-disinfectors, for reprocessing flexible endoscopes with the cleaning indicator. SIMICON-RI or bioindicator SIMICON WD-EF format: \varnothing 1.0 mm x 2 m	WD-E	1 pcs

A



B



C



D



E



Quality Monitoring & Assurance - Cleaning & Disinfection Monitoring Blood-Based Test

CLEANING INDICATORS AND TEST BODIES

Cleaning indicators and test bodies for the verification of Endoscope Washer Disinfector (WD-E) cleaning cycle. Indicators consist of a blood compound and a test body to meet EN 15883.

REF	Description	Qty
A 08029	test body made of stainless steel to check the cleaning efficacy of endoscope washer disinfector, format: \varnothing 2.0mm x 2m	1 pc
B 08030	Olympus® washer-disinfectors adapter for test body REF 08029	1 pc
C 08031	belimed and BHT adapter set for test body REF 08029 - includes pressure box system	1 pc
D 08115	control kit for the cleaning efficacy of endoscope washer-disinfectors consists of: 50x pieces of indicators Simicon RI (REF 08008) 1x test model made of plastic (REF PM-RIBI-2-PP) blue ring: for PC test models, temperature resistant up to 60 °C ring: for V2A test models, temperature resistant up to 121 °C	1 pc



Quality Monitoring & Assurance - Sterilization Monitoring

STEAM STERILIZATION BOWIE-DICK TEST

The Bowie-Dick test is a steam penetration test used as a routine check for the fractional vacuum process in steam sterilizers. It meets EN ISO 11140-4 tests for quality assurance of sterilization process.

REF	Description	Content	Qty
A 08122	BDpro set	1x test body 1x bracket 1x screw with sealing ring for self-test	1 Set
A 08122M	BDpro Type 2 sample set	11x test body 250 strips of 6-level indicators 1x empty box 1x bracket 2x sealing rings 1x screw	1 Set
B 08126	Bdpro tube	1x test body 1x bracket 1x sealing ring screw with sealing ring for self-test	1 Set
C 08123	indicator refill pack for 121 °C – 15 min. / 134 °C – 5 min. (suitable for REF 08122 and 08126)	250 strips of 6-level indicators 1x sealing ring	250 pcs



Quality Monitoring & Assurance - Sterilization Monitoring



BATCH TEST INCL. HOLLOW BODY FOR LARGE STEAM STERILIZERS

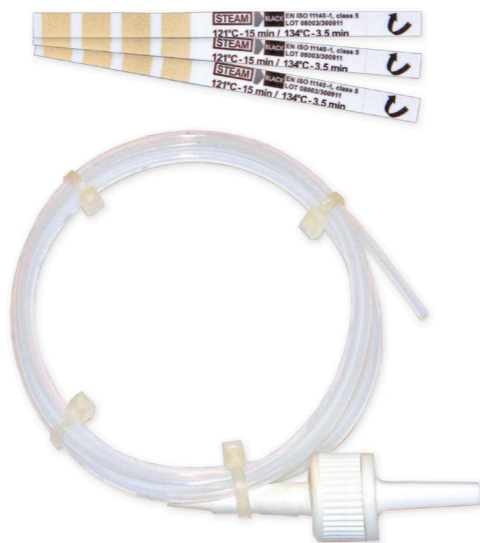
The routine control using test bodies is not only required in DIN EN ISO 17665-1, but also recommended by the Robert Koch Institute (German health organization) for information on ventilation, steam quality and steam penetration in hollow bodies. The Key Surgical LCpro serves as a batch-dependent process control for steam sterilizers.

REF	Description	Content	Qty
A 08120	LCpro set	1x test body 500 strips of 4-level indicators 1x bracket 2x sealing rings screw with sealing ring for self-test	1 set
A 08120M	LCpro type 2 sample set	1x test body 50 strips of 4-level indicators 1x bracket 2x sealing rings 1x screw	1 set
B 08125	LCpro tube test body	1x test body 1x bracket screw with sealing ring for self-test	1 set
C 08121	indicator refill pack for 134 °C-3.5 min. (suitable for REF 08120)	500 strips of 4-level indicators	500 pcs
08145	LCpro set	1x test body 400 strips of 4-level indicators 1x bracket 2x sealing rings screw with sealing ring for self-test	1 set
D 08130	indicator refill pack for 134 °C-18 min. (suitable for REF 08120)	200 strips of 4-level indicators 1x sealing rings	1 set

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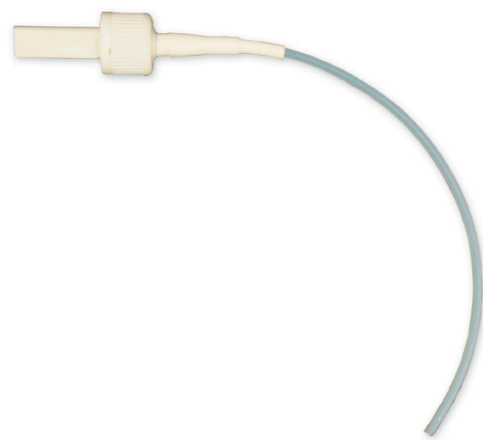
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C



D



Quality Monitoring & Assurance - Sterilization Monitoring

BATCH CONTROL FOR SMALL STEAM STERILIZERS

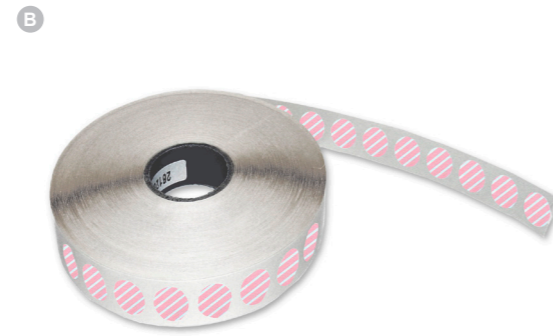
The LCpro Mini Set is suitable for batch monitoring of the sterilization process of small steam sterilizers of class B. Reduce your clinical waste with the help of a reusable test body made of resistant materials. The 4-step indicator becomes black when the process has been successfully completed, enabling a quick interpretation of the result. It can be kept in your documentation for track and trace purposes.

REF	Description	Content	Qty
A 08134	LCpro Mini-Set	1x test body 250 strips of 4-level indicators 1x sealing ring	1 set
A S_08134	LCpro Mini, test system	1x test body 20 strips of 4-level indicators 1x bracket 1x sealing ring	1 set
A 08136	LCpro Mini test body	1x test body 1x sealing ring	1 pc
A 08135	LCpro Mini refill indicators	250 strips of 4-level indicators	250 pcs

HELIX TEST

REF	Description	Properties	Qty
B 08003	Helix Test - steam control indicator - type 5	steam: 134 °C - 3.5min., 121 °C - 15 min. format: 6 x 74mm self-adhesive with color comparison	1 box
C 08087	Helix Test - test model for steam, gas and H ₂ O ₂ sterilization - type 2	material: 1.5m long, reusable PTFE hose (Teflon™), Inner Ø 2mm. The test body also meets the requirements of DIN 58948, EN 14180 and the EN 13060	1 pc
D 08088	Helix Test - test model for steam, gas and H ₂ O ₂ sterilization type 2	material: 2.0m long, reusable PTFE hose (Teflon™), Inner Ø 2mm. The test body meets the requirements of DIN 58948, EN 14180 and the EN 13060	1 pc

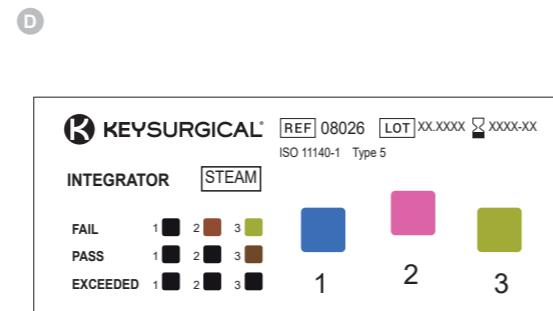
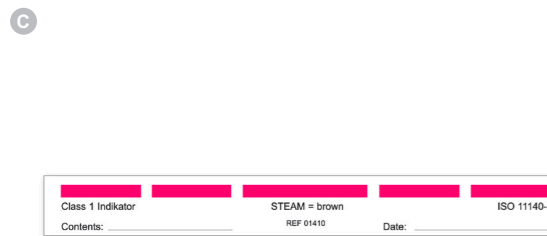
Quality Monitoring & Assurance - Sterilization Monitoring



INDICATOR POINTS AND STRIPS FOR STEAM STERILIZATION

We offer indicators in various designs for additional quality assurance. The indicator points serve as quick evidence that a sterilization process parameters have been met.

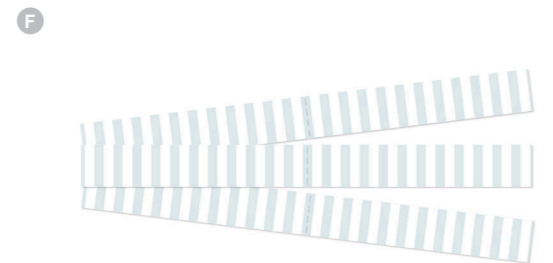
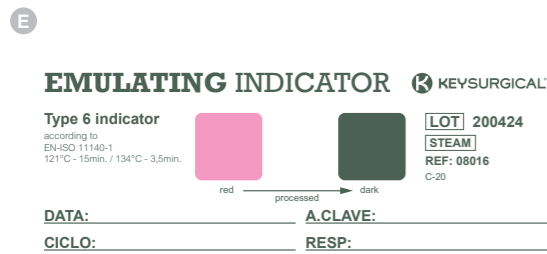
REF	Description	Properties	Qty
A 01401	indicator point, self-adhesive	with steam indicator Ø 10mm	1 roll
B 01159	indicator point, self-adhesive	with steam indicator Ø 15mm	1 roll
C 01410	indicator strips	with steam indicator format: 20 x 170mm	1000 pcs
D 08026	three-phase indicator - type 5	steam: 121 °C / 134 °C 200 strips	1 box
E 08016	steam control indicator - type 6	steam: 134 °C - 3.5 min., 121 °C - 15 min 1x test body 250 strips	1 box



INDICATORS FOR HOT AIR STERILIZATION

The self-adhesive, pre-cut and perforated indicator makes documentation easier because it can be glued to the five documentation sheets supplied during use. The indicator strip is compatible with hot air sterilization at 180 °C for 30 minutes. The given color comparison ensures a comfortable, easy and safe evaluation.

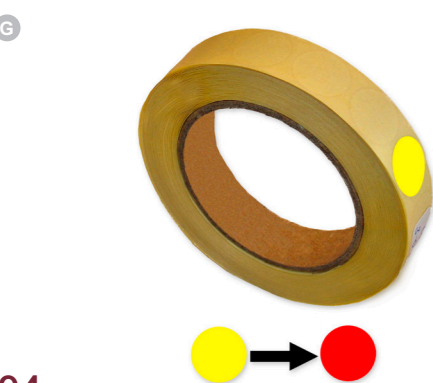
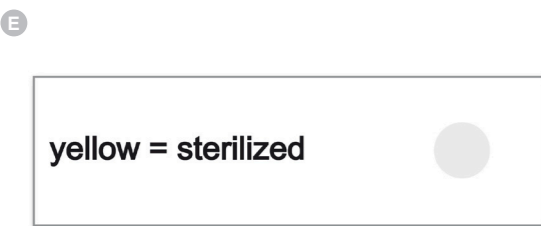
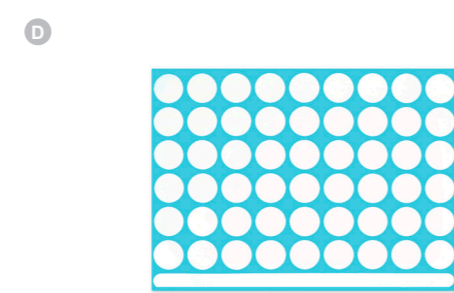
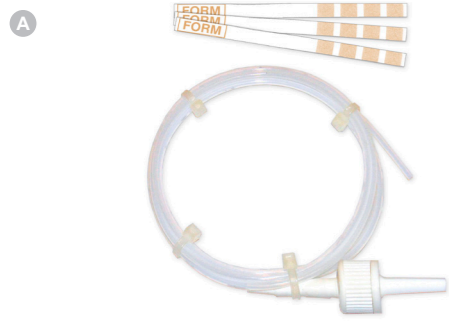
REF	Description	Properties	Qty
F 08002	hot air indicator - type 4	thermo-control: 180 °C - 30 min format: 9 x 48mm box: 120 strips	1 box



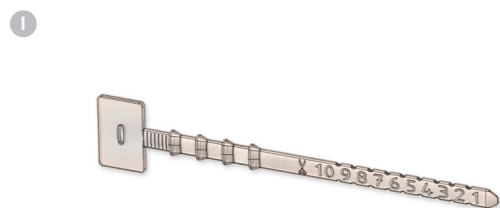
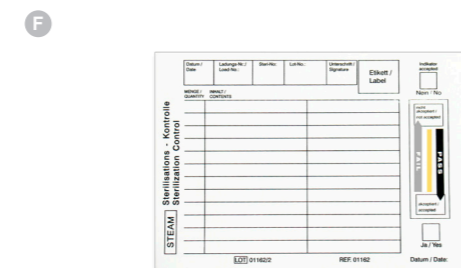
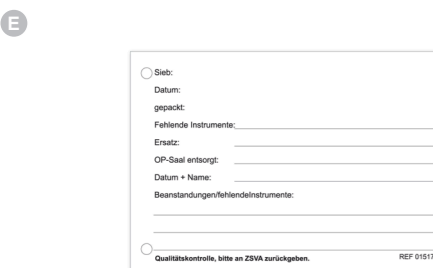
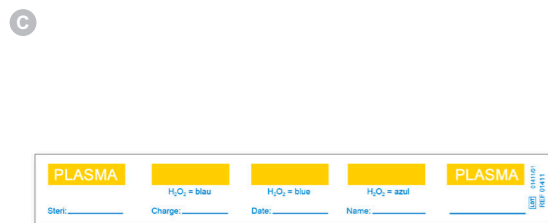
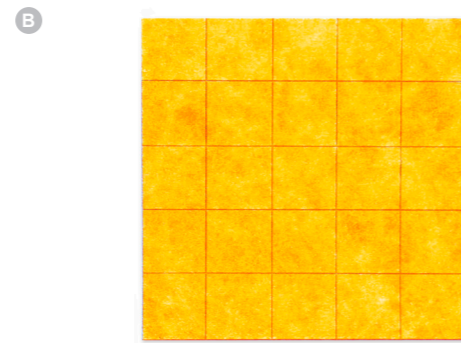
Quality Monitoring & Assurance - Sterilization Monitoring

INDICATORS FOR EO, FO AND GAMMA STERILIZATION

REF	Description	Content	Qty
A 08006	Helix Test - formaldehyde Indicator - Type 4	format: 6 x 74mm self-adhesive with color comparison 1x test body box: 200 strips	1 set
B 01415	indicator point, self-adhesive	with FO indicator, color change from purple to green format: 16 x 22mm	840 pcs
C 01414	indicator point with text, self-adhesive	with EO indicator Ø 15mm	1 roll
01408	indicator point, self-adhesive	with EO indicator Ø 16mm	1080 pcs
D 01407	indicator strips, self-adhesive, with rear slit	with EO indicator format: 15 x 50mm	1000 pcs
E 01419	indicator strips	with EO indicator format: 20 x 100mm	1000 pcs
F 01405	indicator strips, self-adhesive, with rear slit	with EO indicator format: 20 x 170mm	1000 pcs
01418	gamma indicator point, self-adhesive	Ø 12.5mm dose range:> 10 kGy (> 1mrad) 5000 pieces per roll	1 roll
G 01417	gamma indicator point, self-adhesive	Ø 12.5mm dose range:> 10 kGy (> 1mrad) 1000 pieces per roll	2 rolls



Quality Monitoring & Assurance - Sterilization Monitoring



INDICATORS FOR H₂O₂ STERILIZATION

REF	Description	Content	Qty
A 08102	Helix Test - batch control with H ₂ O ₂ indicator	color change from pink to yellow self-adhesive 1x test body box: 100 strips	1 set
B 01413	indicator point, self-adhesive	with H ₂ O ₂ indicator Tyvek format: 10 x 10 mm	500 pcs
C 01411	indicator strips, self-adhesive, with back slit	with H ₂ O ₂ indicator Tyvek, format: 20 x 170 mm	200 pcs

QUALITY DOCUMENTATION

REF	Description	Format (mm)	Qty
D 01504	quality control card with steam indicator	140 x 100	1000 pcs
E 01517	quality control card without indicator	140 x 100	1000 pcs
F 01162	sterilization control card with steam indicator	148 x 105	1000 pcs
G 01412	sterilization protocol for the H ₂ O ₂ sterilization	A4 sheets	50 pcs
H 09243	counting strips suitable for 10 cycles (imprinted no. 1-10) to count reprocessing cycles. Made of plastic. Compatible with washer-disinfectors and steam sterilization	NA	200 pcs
I 09247	counting strips for 10 cycles (imprint no. 1-10) suitable for reprocessing cycles. Made of silicone. Compatible with washer-disinfectors and steam sterilization.	NA	100 pcs



Quality Monitoring & Assurance - Monitoring Equipment

Our test equipment is designed to help you in a wide variety of areas in the CSSD to maintain a high quality standard. The test aid set is an innovative all-in-one one solution designed to support routine checks of surgical instruments.

TEST AID SET IN ACCORDANCE WITH DIN 58298

For testing the functionality of surgical instruments.



REF	Description	Qty
A 08500	test - equipment includes: <ul style="list-style-type: none"> • for bone splitters, hollow chisel forceps and bone punches: cardboard 160 gsm • for traumatic clamps, paper 30 gsm, polybag 50 µm • for surgical scissors, latex strap, styrene-butadiene rubber • for chisels, raspatories, bone curettes and sharp spoons: plastic round profile • for needle holder, wire 0.4 / 0.6 / 0.8 / 1.0mm, PTFE strap 0.2 mm • for non-cutting conchotome, synthetic film with a strength of 300 µm • for forceps, plates made of synthetic material 1.0 / 1.5 / 2.0 / 2.5 / 3.0 / 4.0mm, • for scalpels, knives and cutting conchotome, synthetic film with a strength of 100-µm test drum made of synthetic material • magnifying glass with 5X zoom 	1 set

REFILL ITEMS FOR TEST AID SET

According to DIN 96298-3.

REF	Description	Qty
95172	cardboard, 160 gsm	50 pcs
95141	synthetic foil with a strength of 100 µm	100 pcs
95140	test drum	1 pc
08502	red latex tape, 100% latex, powdered with talc	1 pc
95169	round profile with a diameter of 6mm	1 pc
95154	plates made of synthetic material 1.0 / 1.5 / 2.0 / 2.5 / 3.0 / 4.0mm, each	3 pcs
95143	paper pack, 30 gsm	1 pc
95155	wire 0.4 / 0.6 / 0.8 / 1.0mm each	10 pcs
95139	synthetic foil with a strength of 300 µm	50 pcs
08534	styrene-butadiene rubber NR-SBR	1 pc
09912	polybag 50 µm	1000 pcs
1904180	hand magnifying glass, 4x zoom with led	1 pc
B 08509	monocular magnifying glass, 10x zoom	1 pc





REFILL ITEMS FOR TEST AID SET

According to DIN 96298-3.

REF	Description	Magnification	Properties	Qty
A 09973	3 LED magnifying lamp (white) 10 W	2.5 times lens: 150mm	table lamp with articulated arm (80cm). Attachment: table clamp with screw fastening. Clamping area: 6.5cm on / off switch on the lamp foldable cover for protection of the real glass lens. Easy to clean with internal springs. Light color: daylight (6500K). Operating voltage 230 V.	1 pc
09974	wall bracket	NA	for magnifying lamps REF 09973	1 pc
B 09988	replacement fluorescent ring 12 W NA	NA	for magnifying lamps REF 09978	1 pc



Quality Monitoring & Assurance – Monitoring Equipment for Sealing Devices & Accessories



INKCHECK® SEAL TIGHTNESS TEST

Suitable for routine testing of sealed seams in accordance with DIN EN ISO 11607-1, Annex B. Each set of InkCheck consists of 50 ampules with 2 ml indicator solution and a magnifying glass card (REF 08529). InkCheck offers easy handling twist-off cap aiming to reduce spills and drips, suitable for all standard packaging paper/Tyvek®. The new generation of the seal seam tightness test InkCheck Plus provides simple and clean handling in one step. Single use.

REF	Description	Qty
A 08101	InkCheck	50 pcs
B 08116	InkCheck Plus	30 pcs
B 08124	InkCheck Plus Tyvek	30 pcs



C SEAL PROOF

Seal Proof helps you validate sealers. Single use. Deviations in the sealing process, temperature and the contact pressure are shown on the indicator strip. All this in three simple steps:

1. Place Seal Proof in a cling-free clear pouch
2. Run through the sealing device once
3. Evaluate color change

REF	Description	Format (mm)	Qty
08011	for transparent bags (paper foil)	173 x 91	250 pcs
08017	for Tyvek bags (Tyvek film)	172 x 90	100 pcs

