

sp medikal

key solutions for today 's cssd



CSSD Consumables 2018

sp medikal
key solutions for today 's cssd



INTRODUCTION

CSSD Consumables 2018

SP Medikal San Ltd Sti, based in Istanbul - Turkey, with a European management, is dedicated to the development, production and distribution of Sterility Assurance Products in accordance with the latest international standards.

SP Medikal combines over 30 years of experience, expertise and know-how by its founding partners with markets in Africa, Asia, Europe, Middle East, and South-America.

Due to this broad experience, SP Medikal is offering a complete product range of CSSD Products and services which meets the requirements and needs of today's Central Sterile Supply Departments in Healthcare facilities.

Over more than 65 countries are served by SP Medikal through exclusive distributors and over 25 countries through her second production facility CSB Medical in South-America.

The Sterility Assurance Products SP Medikal provides can be categorized into 6 groups i.e.

Sterilizer Monitoring
In-Pack Monitoring
Documentation / Traceability
Sterile Barrier Systems
Cleaning / Disinfection
Accessories

All **Sterintech™** branded products are produced and/or assembled in our up-to-date production facility. The development, production and packaging of our products are meeting our quality assurance procedures as laid down in our ISO 13485 quality manual accredited by KIWA.

SP Medikal is a GMDN registered manufacturer and has a Medical Device Manufacturer's certificate and registration by the Turkish Government.

Medical Devices amongst our product range are CE-marked and certified and fulfill requirements of Medical Device Directive 2017/745 EU.

Our products comply with the requirements as laid down in the latest versions of the following standards:

EN 285
EN 865 / 866 / 867 / 868
ISO 11138
ISO 11140
ISO 11607
ISO 13060

All our products are carrying our brandname **Sterintech™** but are also available as OEM product.



List of Content

Sterilizer Monitoring Type 2 and BI

- Bowie Dick Tests
- Batch Monitoring / Cycle verification
- Biological Indicators

In-Pack Monitoring Type 4, 5 and 6

- In-Pack Indicators, Integrators and Emulators

Sterile Barrier Systems

- Sterilisation rolls (Flat , Gusseted , Tyvek)
- Soft Crepe
- SMS Non-Woven
- Seal Check
- Tapes

Documentation / Traceability

- 2 Line label gun and labels
- 3 Line label gun and labels
- Thermo Transfer Labels with indicators

Cleaning / Disinfection

- Protein Swab Test
- WD test (launch in 2018)

Accessories

- Container Cards
- Container Filters
- Container Seals
- Self-adhesive Container seals

- Instrument Protector / Instrument Fix
- Instrument tray corner protection
- CSSD Markers
- Sticky mats
- Water Soluble bags



BOWIE DICK TEST

Since 1963 the standard test for steam sterilizers with pre-vacuum cycles the Bowie Dick Test Pack is an obligatory test for any steam sterilizer used to sterilize Medical Devices.

A variety of Bowie Dick tests are available. From Bowie Dick Test sheets to Bowie Dick Test Pack but also a Bowie Dick Helix Test for bench top steam sterilizers.

Characteristics of the Bowie Dick Test Packs:

- Disposable Single Use pack
- Clear color change of indicator
- No lead, non toxic
- Lot number on indicator sheet
- Indicator sheet can be kept as record for up to 10 years





BOWIE DICK TEST PACK

Ref.: 102.002.0020

BDTP Blue - Pink

Unit: 20 packs

BOWIE DICK HELIX TEST

Ref.: 101.201.0100

BDHT Blue - Pink

Unit: 100 indicators

Ref.: 101.201.0250

BDHT Blue - Pink

Unit: 250 indicators

All sets comes with cotton bag, Helix device, manual and color reference



BOWIE DICK SHEET

Ref.: 102.010.0050

BD test sheet A4

Unit: 50 sheets

Ref.: 102.011.0050

BD test sheet A5

Unit: 50 sheets

BOWIE DICK HELIX TEST (SS)

Ref.: 101.203.0100 BDHT (SS) with stainless steel Helix Unit: 100 indicators

Ref.: 101.203.0250 BDHT (SS) with stainless steel Helix Unit: 250 indicators

All sets comes with cotton bag, stainless steel Helix device, manual and color reference

Ref.: 101.205.0500 Re-fill set with only indicators Unit: 500 indicators

Sets comes with cotton bag, manual and color reference





BATCH MONITORING / Cycle verification

In these days that the main category of products sterilized at the CSSD is consisting out of instrument trays and containers with instruments, which are getting more and more complex by having narrow lumen inside, the challenge is to reach sterilization conditions even inside those complex instruments.

Monitoring sterilization conditions inside pouches and containers by the use of a Type 4, 5 and/or 6 indicator strips is practiced in a lot of our markets but the Batch Monitoring by the use of Helix devices is recommended more and more by international and national institutes and governmental organizations.

Helix devices have proven to detect sterilization problems earlier and as such enhances quality control at the sterilization department. A few unique failure detection by Helix devices:

- Insufficient vacuum
- Insufficient air removal from hollow devices
- Insufficient steam penetration in hollow devices
- Leakage of piping valves seals
- Detection of presence of small volume inert gases
- Detection of excessive amounts of condensate
- Different load conditions

Compared to the use of Biological indicators the Helix Batch Monitoring is more economic and quicker in terms of use and interpretations. No need to wait for any incubation period but an immediately release of sterilized goods is possible based upon the sterilizer parameters, check on loads as well as interpretation of the Helix indicator.

Batch Monitoring by Helix devices is available for many kinds of sterilization methods like Steam, Formaldehyde, Ethylene-oxide as well as Plasma sterilization.

A relatively cost-effective, high secure test which contributes to the decision on whether Medical Devices have been successfully sterilized. The reason to SP Medikal to support and promote the Helix device as Batch Monitoring likewise other international and national institutes are doing.



BATCH CONTROL HELIX TEST STEAM

103.203.0100 BCHT Type 2 indicators 121°C-15 min / 134°C-3,5 min	Unit: 100 ind.
103.203.0250 BCHT Type 2 indicators 121°C-15 min / 134°C-3,5 min	Unit: 250 ind.
103.203.0500 BCHT Type 2 indicators 121°C-15 min / 134°C-3,5 min	Unit: 500 ind.
103.005.0100 BCHT Type 2 indicators 121°C-20 min / 134°C-5,0 min	Unit: 100 ind.
103.007.0100 BCHT Type 2 indicators 134°C-7,0 min	Unit: 100 ind.
103.018.0100 BCHT Type 2 indicators 134°C-18,0 min	Unit: 100 ind.

All sets comes with cotton bag, Helix device, manual and color reference

BATCH CONTROL HELIX TEST PLASMA

103.020.0100 BCHT Type 2 indicators VH202	Unit: 100 ind.
---	----------------

All sets comes with Helix device, manual and color reference

BATCH CONTROL HELIX TEST FORM

103.040.0100 BCHT Type 2 indicators FORM	Unit: 100 ind.
--	----------------

All sets comes with Helix device, manual and color reference

BATCH CONTROL HELIX TEST EO

103.230.0100 BCHT Type 2 indicators EO (600 mg/ltr)	Unit: 100 ind.
103.230.0250 BCHT Type 2 indicators EO (600 mg/ltr)	Unit: 250 ind.
103.230.0500 BCHT Type 2 indicators EO (600 mg/ltr)	Unit: 500 ind.

All sets comes with Helix device, manual and color reference



BIOLOGICAL INDICATORS

The monitoring of sterilization conditions at preferred places inside a load / cycle with Self Contained Biological Indicators (SCBI) is widely used for daily routine checks in Hospitals. The frequency and application however differs a lot per region / country and is determined by local guidelines and directives.

Available for Steam, Formaldehyde, Ethylene-oxide as well as Plasma sterilization SP Medikal is offering a high qualitative SCBI, removable label with process indicator with all relevant data on it like a lot number and expiry date.

As Biological Indicators as such are not able to detect failures like leakages, Inert or non-condensable gases and others, SP Medikal advises to use a BI Helix Device in combination with the SCBI. The BI Helix Device is a Process Challenging Device which enables the SCBI to detect the earlier mentioned failures.

Characteristics :

SCBI conforms to ISO 11138
Available for 24 hrs and 3 hrs (rapid read-out) incubation time

SCBI STEAM / PLASMA / FORM :

Geobacillus stearothermophilus ATCC 7953 , population 1×10^6

SCBI EO

Bacillus Athrophaeus ATCC 9372 , population 1×10^6

DIGITAL INCUBATOR

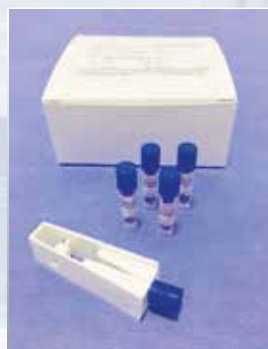
The **Sterintech™** Digital Incubator for SCBI has been specially designed for the incubation of SCBI. It has 2 different cycles specifically for all different SCBI products.

With a capacity of 18 holes it is one of the largest incubators in this field giving more flexibility and capacity for users in Hospitals.

Equipped with a micro-processor control and a digital display it is highly accurate in keeping temperature at on of the set levels. Upon completion of the incubation time the unit will switch off the incubation and give an audible and visual alarm.

Available for 100-220V / 50-60 Hz

Cycles: 37°C / 48 hrs (EO)
59°C / 24 hrs (Steam, Plasma , FO)



SCBI STEAM

107.001.0100 SCBI STEAM Bac. Stearothermophilus 1×10^6 Unit: 100 pieces
120.010.0001 Crusher Unit: 1 piece

NEW

107.010.0050 SCBI STEAM 'Quick read-out' -3hr.

SCBI PLASMA

107.002.0100 SCBI Plasma Bac. Stearothermophilus 1×10^6 Unit: 100 pieces
120.010.0001 Crusher Unit: 1 piece

NEW

107.020.0050 SCBI PLASMA 'Quick read-out' -3hr.

SCBI EO

107.003.0100 SCBI EO Bac. Atrophaeus 1×10^6 Unit: 100 pieces
120.010.0001 Crusher Unit: 1 piece

SCBI FORM

107.004.0100 SCBI Form Bac. Stearothermophilus 1×10^6 Unit: 100 pieces
120.010.0001 Crusher Unit: 1 piece

DIGITAL INCUBATOR

120.001.0001 Incubator with 18 holes and three standard programs for Steam, Plasma and Ethylene-Oxide - 220 V - 50 Hz. Unit: 1 piece

Digital micro-processor controlled with small digital display to give a feed-back about temperature and remaining time.

120.002.0001 : Digital Incubator SCBI Quick read-out, 8 ampoule
For steam and plasma - 220 V - 50 Hz. Unit: 1 piece

IN-PACK INDICATORS

The sole reason to use an in-pack indicator, whether it is a Type 4, 5 or 6, should be to detect and monitor the sterilization conditions inside packs, trays or containers.

By using these in-pack indicators, the Operating Theatre is giving a proof of sterilization conditions inside the packs and containers.

Many of our in-pack indicators do offer a self-adhesive backing in order that the Operating staff can glue these indicators into the patient records for future reference. A wide variety of in-pack indicators, integrators, emulators are available for all commonly used sterilization methods i.e. Steam, Formaldehyde, Ethylene-oxide as well as Plasma sterilization.

The in-pack indicators are compliant to ISO 11140-1 : 2014.

TYPE 4 INDICATORS - STEAM - SELF-ADHESIVE ON ROLL

104.010.0500 Type 4 Indicators on roll with dispenser box Unit: 500 indicators

TYPE 4 INDICATORS - PLASMA - SELF - ADHESIVE ON ROLL

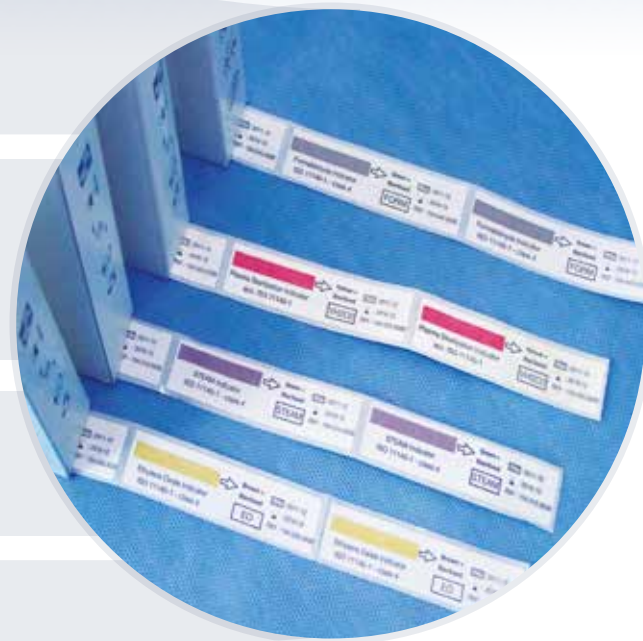
104.020.0500 Type 4 Indicators on roll with dispenser box Unit: 500 indicators

TYPE 4 INDICATORS - EO - SELF - ADHESIVE ON ROLL

104.030.0500 Type 4 Indicators on roll with dispenser box Unit: 500 indicators

TYPE 4 INDICATORS - FORM - SELF - ADHESIVE ON ROLL

104.040.0500 Type 4 Indicators on roll with dispenser box Unit: 500 indicators



TYPE 4 INDICATORS - STEAM

104.003.0500 Type 4 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 500 pcs



TYPE 4 INDICATORS - LONG STRIP - STEAM

104.004.0250 Type 4 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 2x250 pcs



TYPE 5 INTEGRATOR - SEQUENTIAL - STEAM

105.103.0500 Type 5 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 500 pcs
 105.203.0500 Type 5 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 500 pcs
 105.018.0250 Type 5 indicator strip 134°C -18 min Unit: 250 pcs



TYPE 5 INTEGRATOR MF - STEAM

105.103.1000 Type 5 Moving Front 121°C -15 min/134 °C 3,5 min Unit: 1000 pcs



TYPE 6 EMULATOR - STEAM

106.103.0500 Type 6 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 500 pcs
 106.203.0500 Type 6 indicator strip 121°C -15 min/134 °C -3,5 min Unit: 500 pcs
 106.007.0250 Type 6 indicator strip 134°C -7 min Unit: 250 pcs
 106.018.0250 Type 6 indicator strip 134°C -18 min Unit: 250 pcs



TYPE 4 INDICATORS - PLASMA

104.022.0200 Type 4 indicator strip Unit: 200 pcs



TYPE 5 INTEGRATOR - EO

105.030.0500 Type 5 indicator strip Unit: 500 pcs



TYPE 5 INTEGRATOR - FORM

105.040.0500 Type 5 indicator strip Unit: 500 pcs



STERILIZATION ROLLS

Sterilizing Medical Devices is one but keeping them sterile is another subject.

The **Sterintech™** Sterilization rolls are compliant to ISO 11607 and are manufactured under our ISO 13485 quality assurance standard.

In combination with the specifications of the European raw materials, it ensures that the end-product is compliant to the latest standards. In that respect SP Medikal can guarantee that the product till the expiry date is compliant to designated specifications and fulfills the requirements of CSSD needs.

Often Hospitals ask how long items can be kept sterile once sterilized. A simple question which is not easy to answer since the sterility of sterilized items is not depending on time only but more upon the conditions under which the sterile goods are transported and stored.

Examples of events:

- Chance of damages occurring during transportation
- How is it packed (single / double / kind of sterile barrier)
- Method of sterilization
- Method of transportation
- Storage conditions

All these parameters determine the shelf life of sterile goods. If needed SP Medikal can provide a handy guideline to determine the shelf life of sterile goods.

Characteristics Paper - Film Rolls:

- ISO 11607-1 & 2 and EN 868-3 & 5 compliant
- Medical grade paper (60 and 70 g/m²) EN 868-4 compliant
- Tear-proof film (min. 5 layers) , green
- Three chemical indicators (ISO 11140-1 ,Type 1)
- Safe print outside the packing area
- Three strong seals at each side (total 1 cm width)
- Unique **Precise-seal™** sealing technology
- Lot number printed on the roll
- Wide range of sizes - customized sizes available
- Excellent , clean, fibre-free opening

Precise-seal™

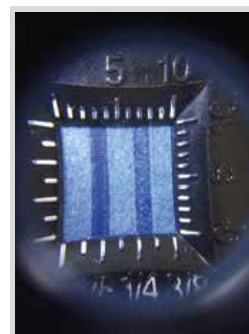
The **Precise-seal™** technology developed by SP Medikal makes the side seal of our sterilization rolls stronger and consistent. Due to a special heat-up and rolling sealing technology the side seals of our sterilization rolls prevents typical sealing issues while using bar sealing methods. Typical problems of bar sealing are:

- Alignment issues
- Steam forming issues
- Clean peel issues

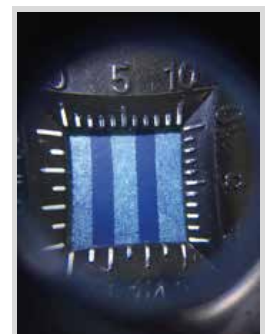
To see the difference between a bar sealing result and a **Precise-seal™** result we show you the detailed pictures of both seals :

Characteristics Tyvek® Film Rolls:

- EN ISO 11607- 1 & 2 and EN 868-3 & 5 compliant
- Tyvek® 60 g/m²
- Tear-proof film (min. 5 layers) , white
- One chemical indicator (ISO 11140-1 , Type 1)
- Safe print outside the packing area
- Three strong seals at each side (total 1 cm width)
- Lot number printed on the roll
- Wide range of sizes - customized sizes available
- Excellent , clean, fibre-free opening



Bar sealing result



Precise-seal™ results



STERILIZATION ROLLS - FLAT

52um Green multi-layer film - 60 gr/sqm - Medical grade paper

301.050.0001	Dimension 50 mm x 200 m	Unit = 1 roll
301.075.0001	Dimension 75 mm x 200 m	Unit = 1 roll
301.100.0001	Dimension 100 mm x 200 m	Unit = 1 roll
301.150.0001	Dimension 150 mm x 200 m	Unit = 1 roll
301.200.0001	Dimension 200 mm x 200 m	Unit = 1 roll
301.250.0001	Dimension 250 mm x 200 m	Unit = 1 roll
301.300.0001	Dimension 300 mm x 200 m	Unit = 1 roll
301.350.0001	Dimension 350 mm x 200 m	Unit = 1 roll
301.400.0001	Dimension 400 mm x 200 m	Unit = 1 roll

STERILIZATION ROLLS - GUSSETED

52um Green multi-layer film - 60 gr/sqm - Medical grade paper

302.075.0001	Dimension 75 mm x 100 m	Unit = 1 roll
302.100.0001	Dimension 100 mm x 100 m	Unit = 1 roll
302.150.0001	Dimension 150 mm x 100 m	Unit = 1 roll
302.200.0001	Dimension 200 mm x 100 m	Unit = 1 roll
302.250.0001	Dimension 250 mm x 100 m	Unit = 1 roll
302.300.0001	Dimension 300 mm x 100 m	Unit = 1 roll
302.350.0001	Dimension 350 mm x 100 m	Unit = 1 roll
302.400.0001	Dimension 400 mm x 100 m	Unit = 1 roll



STERILIZATION ROLLS - TYVEK

52um White multi-layer film - Tyvek material

303.075.0001	Dimension 75 mm x 70 m	Unit = 1 roll
303.100.0001	Dimension 100 mm x 70 m	Unit = 1 roll
303.150.0001	Dimension 150 mm x 70 m	Unit = 1 roll
303.200.0001	Dimension 200 mm x 70 m	Unit = 1 roll
303.250.0001	Dimension 250 mm x 70 m	Unit = 1 roll
303.300.0001	Dimension 300 mm x 70 m	Unit = 1 roll
303.350.0001	Dimension 350 mm x 70 m	Unit = 1 roll
303.400.0001	Dimension 400 mm x 70 m	Unit = 1 roll
303.500.0001	Dimension 500 mm x 70 m	Unit = 1 roll

Sterile Barrier Systems

SMS Non Wovens

Sterintech™ SMS can be used as an inner and outer wrap and serve as a sterile field at the point of use. The M-layer is sandwiched between two S-layers which are larger and stronger, provide exceptional strength as well as tear, burst, and abrasion resistance.

The **Sterintech™** SMS materials are characterized by the following:

- Available standard as 43 gsm, optional 60 gsm
- Microbial Barrier
- Water and alcohol repellent
- Serve as Infection prevention measure
- High resistance to puncture, burst, abrasion and tearing
- Soft, Strong and memory free
- Not containing Cellulose nor synthetic binder
- Not containing natural rubber latex
- Compatible for STEAM, EO and Plasma Sterilization methods
- Compliant to standard ISO 11607-1 and EN 868-2
- European Guideline 94/62 (heavy metals in packaging)
- Compliant to the provisions of the MDD 2017/745 EU

Available in standard as well as customer specific dimensions.

Tapes

The **Sterintech™** Indicator tapes are used to tape the packaging materials of wrapped instrument trays. Next to a good stickiness the Tapes provide in a ISO 11140 - 1 Type 1 chemical indicator (except 501.019.0048 and 501.025.0036) to distinct processed and unprocessed instrument trays.

The **Sterintech™** Indicator tapes are produced on mother rolls and cut into the various width while re-winded on smaller inner cores. Two widths are offered i.e. 19mm and 25 mm, both having a length of 50 mtr.

TAPES FOR STEAM

501.019.0048 White tape without indicator, 19 mm x 50 m	Unit: 48 pieces
501.025.0036 White tape without indicator, 25 mm x 50 m	Unit: 36 pieces
502.019.0048 White tape with steam indicator, 19 mm x 50 m	Unit: 48 pieces
502.025.0036 White tape with steam indicator, 25 mm x 50 m	Unit: 36 pieces
512.019.0048 Blue tape with steam indicator, 19 mm x 50 m	Unit: 48 pieces

Soft Crepe

Today's infection control is getting increasingly important since more bacteria's start to get resistant to the latest Anti-biotics.

Infection prevention and control are the keywords.

Soft Crepe papers and / or SMS Non-Wovens are essential for both Sterility Assurance and Infection Prevention in its function as Sterile Barrier for sterilized Medical Devices.

Soft Crepe (Green, Blue and Blue/Green mix)

Sterintech™ Soft Crepe papers can be used as an inner or outer wrap and serve as a sterile field in combination with Non-Wove and/or Textile materials.

The **Sterintech™** Soft Crepe papers are characterized by the following :

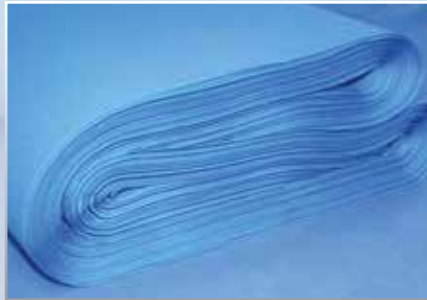
- Microbial Barrier
- Water repellent
- Serve as Infection prevention measure
- High resistance to puncture and tearing
- Soft, Strong and memory free
- Compatible for STEAM, FORM or EO Sterilization methods
- Compliant to standard ISO 11607-1 and EN 868-2

Available in standard as well as customer specific dimensions.



TAPES FOR EO & PLASMA & DRY HEAT

503.019.0048 White tape with EO indicator, 19 mm x 50 m	Unit: 48 pieces
504.019.0001 White tape with Plasma indicator, 19 mm x 60 m	Unit: 1 piece
504.025.0001 White tape with Plasma indicator, 25 mm x 25 m	Unit: 1 piece
505.019.0001 White tape with Dry heat indicator, 19 mm x 55 m	Unit: 1 piece



SMS - NON WOVEN - 43 GR/M² - BLUE

224.024.1000	Dimension 24 cm x 24 cm	Unit = 1.000 sheets
224.050.0400	Dimension 50 cm x 50 cm	Unit = 400 sheets
224.060.0400	Dimension 60 cm x 60 cm	Unit = 400 sheets
224.075.0200	Dimension 75 cm x 75 cm	Unit = 200 sheets
224.090.0200	Dimension 90 cm x 90 cm	Unit = 200 sheets
224.100.0200	Dimension 100 cm x 100 cm	Unit = 200 sheets
224.120.0100	Dimension 120 cm x 120 cm	Unit = 100 sheets
224.130.0100	Dimension 130 cm x 150 cm	Unit = 100 sheets

SOFT CREPE - 60 GR/M² - BLUE

202.025.1000	Dimension 25 cm x 25 cm	Unit = 1.000 sheets
202.030.1000	Dimension 30 cm x 30 cm	Unit = 1.000 sheets
202.050.0500	Dimension 50 cm x 50 cm	Unit = 500 sheets
202.060.0500	Dimension 60 cm x 60 cm	Unit = 500 sheets
202.075.0250	Dimension 75 cm x 75 cm	Unit = 250 sheets
202.090.0250	Dimension 90 cm x 90 cm	Unit = 250 sheets
202.100.0250	Dimension 100 cm x 100 cm	Unit = 250 sheets
202.120.0125	Dimension 120 cm x 120 cm	Unit = 125 sheets
202.130.0125	Dimension 130 cm x 150 cm	Unit = 125 sheets

SMS - NON WOVEN - 43 GR/M² - GREEN

205.024.1000	Dimension 24 cm x 24 cm	Unit = 1.000 sheets
205.050.0400	Dimension 50 cm x 50 cm	Unit = 400 sheets
205.060.0400	Dimension 60 cm x 60 cm	Unit = 400 sheets
205.075.0200	Dimension 75 cm x 75 cm	Unit = 200 sheets
205.090.0200	Dimension 90 cm x 90 cm	Unit = 200 sheets
205.100.0200	Dimension 100 cm x 100 cm	Unit = 200 sheets
205.120.0100	Dimension 120 cm x 120 cm	Unit = 100 sheets
205.130.0100	Dimension 130 cm x 150 cm	Unit = 100 sheets

SOFT CREPE - 60 GR/M² - GREEN

212.025.1000	Dimension 25 cm x 25 cm	Unit = 1.000 sheets
212.030.1000	Dimension 30 cm x 30 cm	Unit = 1.000 sheets
212.050.0500	Dimension 50 cm x 50 cm	Unit = 500 sheets
212.060.0500	Dimension 60 cm x 60 cm	Unit = 500 sheets
212.075.0250	Dimension 75 cm x 75 cm	Unit = 250 sheets
212.090.0250	Dimension 90 cm x 90 cm	Unit = 250 sheets
212.100.0250	Dimension 100 cm x 100 cm	Unit = 250 sheets
212.120.0125	Dimension 120 cm x 120 cm	Unit = 125 sheets
212.130.0125	Dimension 130 cm x 150 cm	Unit = 125 sheets

TRACEBILITY / DOCUMENTATION

Proper clear marking and the possibility to trace packed instrument, instrument trays and containers is essential in case of re-calls but also for logistical and patient record keeping.

The Medical Device directive is obliging that all sterile Medical Devices should at least carrying the following information:

- Lot Number
- Packing date
- Expiry date
- Sterile/Non-sterile

All these data can be simply provided by a double 2 Line Label gun label with indicator.

SP Medikal is favoring double labels as the top label can be used for documentation purposes in patient records. When even more data is required by the Operating Theatre the use of a 3 Line Label Gun system and their indicator labels is an option.

For CSSD's using tracing and tacking software which prints barcodes by means of thermo-transfer printers SP Medikal is providing Indicator labels in any size or configuration.

2 LINE LABEL GUN

The **Sterintech™** two line label gun is reliable, easy to use and durable, It will serve for years of intensive usage. **Sterintech™** double labels for two line label guns are available with all type of sterilization indicators as well as a variety of colors.

Colored labels are used to assist FIFO systems as well as easy recognition of sterile goods for a certain department.

Often the combination of a double label gun label and normal tape is a more cost-effective solution than steam tapes only. Next to that they offer better readable data and prevent writing errors.

Characteristics:

- Process Indicators (Steam, F0, E0, Plasma) conform to ISO 11140 1 Type 1
- Clear transition of indicator into its end-color
- Easy to use label gun
- Double labels serve for an easy traceability and documentation
- Non-Toxic Lead Free indicators
- Latex free label materials
- Can be fully recycled



2 LINE LABEL GUN

602.002.0001 2 Line Label gun (3x ABC+11 numbers +14 numbers)	Unit: 1 pc
602.002.0101 2 Line Label gun (7x ABC+ 7 numbers +14 numbers)	Unit: 1 pc
609.102.0001 Ink roller for 602.002.0001 & 602.002.0101	Unit: 1 pc
602.002.0201 Contact 2 Line Label gun	Unit: 1 pc
609.112.0001 Ink roller for 602.002.0201	Unit: 1 pc

2 LINE LABEL GUN - COLORED LABELS

602.101.9000 2 Line Label gun label - blue	Unit = 9.000 labels
602.102.9000 2 Line Label gun label - red	Unit = 9.000 labels
602.103.9000 2 Line Label gun label - green	Unit = 9.000 labels
602.104.9000 2 Line Label gun label - yellow	Unit = 9.000 labels
602.105.9000 2 Line Label gun label - orange	Unit = 9.000 labels
602.106.9000 2 Line Label gun label - grey	Unit = 9.000 labels
602.107.9000 2 Line Label gun label - purple	Unit = 9.000 labels

2 LINE LABEL GUN - INDICATOR LABELS

602.011.9000 2 Line Label gun label - STEAM	Unit = 9.000 labels
602.022.9000 2 Line Label gun label - PLASMA	Unit = 7.200 labels
602.031.9000 2 Line Label gun label - EO	Unit = 9.000 labels
602.040.9000 2 Line Label gun label - FORM	Unit = 9.000 labels

2 LINE LABEL GUN - INDICATOR LABELS - STEAM + COLOR

602.111.9000 2 Line Label gun label - STEAM - blue	Unit = 9.000 labels
602.112.9000 2 Line Label gun label - STEAM - red	Unit = 9.000 labels
602.113.9000 2 Line Label gun label - STEAM - green	Unit = 9.000 labels
602.114.9000 2 Line Label gun label - STEAM - yellow	Unit = 9.000 labels
602.115.9000 2 Line Label gun label - STEAM - orange	Unit = 9.000 labels
602.116.9000 2 Line Label gun label - STEAM - grey	Unit = 9.000 labels
602.117.9000 2 Line Label gun label - STEAM - purple	Unit = 9.000 labels



3 LINE LABEL GUN

603.003.0001 3 Line Label gun MONARCH	Unit = 1 gun
609.103.0001 Ink Roller for 603.003.0001	Unit = 1 piece
603.203.0001 3 Line Label gun Sterintech	Unit = 1 gun
609.203.0001 Ink Roller for 603.203.0001	Unit = 1 piece

3 LINE LABEL GUN - INDICATOR LABELS

603.211.9000 3 Line Label gun label - STEAM	Unit = 9.000 labels
603.220.9000 3 Line Label gun label - PLASMA	Unit = 6.000 labels
603.231.9000 3 Line Label gun label - EO	Unit = 9.000 labels
603.240.9000 3 Line Label gun label - FORM	Unit = 9.000 labels

3 LINE LABEL GUN - INDICATOR LABELS STEAM + COLOR

604.011.9000 3 Line Label gun label - STEAM - blue	Unit = 9.000 labels
604.012.9000 3 Line Label gun label - STEAM - red	Unit = 9.000 labels
604.013.9000 3 Line Label gun label - STEAM - green	Unit = 9.000 labels
604.014.9000 3 Line Label gun label - STEAM - yellow	Unit = 9.000 labels
604.015.9000 3 Line Label gun label - STEAM - orange	Unit = 9.000 labels
604.016.9000 3 Line Label gun label - STEAM - purple	Unit = 9.000 labels

3 LINE LABEL GUN - INDICATOR LABELS + COLOR

603.011.9000 3 Line Label gun label - STEAM	Unit = 9.000 labels
603.021.9000 3 Line Label gun label - PLASMA	Unit = 6.000 labels
603.031.9000 3 Line Label gun label - EO	Unit = 9.000 labels
603.040.9000 3 Line Label gun label - FORM	Unit = 9.000 labels
603.101.9000 3 Line Label gun label - STEAM - blue	Unit = 9.000 labels
603.102.9000 3 Line Label gun label - STEAM - red	Unit = 9.000 labels
603.103.9000 3 Line Label gun label - STEAM - green	Unit = 9.000 labels
603.104.9000 3 Line Label gun label - STEAM - yellow	Unit = 9.000 labels
603.105.9000 3 Line Label gun label - STEAM - orange	Unit = 9.000 labels
603.106.9000 3 Line Label gun label - STEAM - purple	Unit = 9.000 labels



3 LINE LABEL GUN - COLOR

604.111.9000 3 Line Label gun label - blue	Unit = 9.000 labels
604.112.9000 3 Line Label gun label - red	Unit = 9.000 labels
604.113.9000 3 Line Label gun label - green	Unit = 9.000 labels
604.114.9000 3 Line Label gun label - yellow	Unit = 9.000 labels
604.115.9000 3 Line Label gun label - orange	Unit = 9.000 labels
604.116.9000 3 Line Label gun label - purple	Unit = 9.000 labels

3 LINE LABEL GUN - INDICATOR

605.011.9000 3 Line Label gun label - STEAM	Unit = 9.000 labels
605.021.9000 3 Line Label gun label - PLASMA	Unit = 6.000 labels
605.031.9000 3 Line Label gun label - EO	Unit = 9.000 labels
605.040.9000 3 Line Label gun label - FORM	Unit = 9.000 labels

3 LINE LABEL GUN - INDICATOR - BROWNE

605.511.9000 3 Line Label gun label - STEAM	Unit = 9.000 labels
605.520.9000 3 Line Label gun label - PLASMA	Unit = 6.000 labels
605.531.9000 3 Line Label gun label - EO	Unit = 9.000 labels
605.540.9000 3 Line Label gun label - FORM	Unit = 9.000 labels

3 LINE LABEL GUN - COLOR - BROWNE

605.591.9000 3 Line Label gun label - blue	Unit = 9.000 labels
605.592.9000 3 Line Label gun label - red	Unit = 9.000 labels
605.593.9000 3 Line Label gun label - green	Unit = 9.000 labels
605.594.9000 3 Line Label gun label - yellow	Unit = 9.000 labels
605.595.9000 3 Line Label gun label - orange	Unit = 9.000 labels
605.596.9000 3 Line Label gun label - purple	Unit = 9.000 labels

TRACEABILITY / DOCUMENTATION

Thermo Transfer Labels with indicators

SP Medikal has specialized herself on Indicator labels for sterilization purposes. More and more Hospitals start to use computerized tracing and tracking systems which incorporates the use of scanners and therefore the need for barcode printing is mandatory.

Specially designed for thermo-transfer printers and durable to withstand any sterilization cycle up to steam sterilization cycles for 18 min at 134°C

Our standards are high and as European raw materials are the basis for our production the quality of our labels are meeting any design specification.

Some characteristics :

- Latex free
- Reach / ROHS compliant
- High stickiness on all surfaces
- Suitable for barcode printing / reading
- Up to 3 years expiry time

Available as

- Single Label
- Double Label (piggy back)
- One two or even three part label
- With any Chemical indicator (STEAM, EO , FO , Plasma)
- With Steam / EO indicator on one label
- All standard and bespoke dimensions and designs

BLANK LABELS

702.013.1000	Piggy-back Label Three part Dimensions: 70 x 35 mm, ID 76	Unit: 1.000 labels
702.014.1000	Piggy-back Label Three part Dimensions: 102 x 59 mm, ID 76	Unit: 1.000 labels

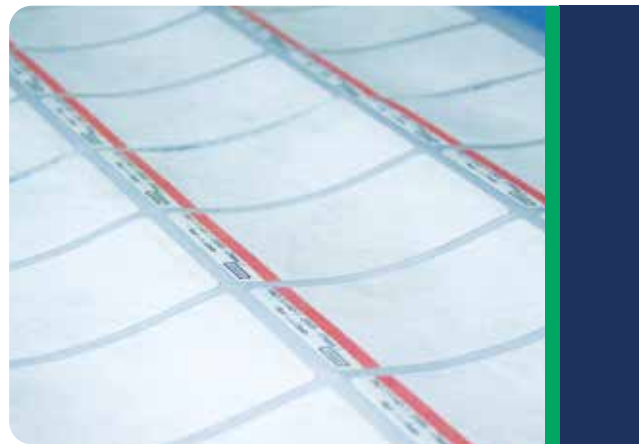


STEAM INDICATOR LABELS

703.002.1000	Single Label - STEAM Dimensions: 59 x 35 mm, ID 25	Unit: 1.000 labels
703.041.1000	Piggy-back Label - STEAM Dimensions: 70 x 35 mm, ID 45	Unit: 1.000 labels
703.039.1000	Piggy-back Label Three part - STEAM Dimensions: 102 x 59 mm, ID 45	Unit: 1.000 labels

PLASMA INDICATOR LABELS

704.004.0500	Piggy Back Tyvek Label - Plasma Dimensions: 70 x 35 mm, ID 45	Unit: 500 labels
--------------	--	------------------



SPOTS

904.001.0010	Self-adhesive Spots 16 x 9 mm - STEAM 10 sheets , each 340 spots	Unit = 3.400 spots
904.004.0010	Self-adhesive Spots 16 x 9 mm - FORM 10 sheets , each 340 spots	Unit = 3.400 spots

ACCESSORIES

WASHER DISINFECTION

Washer Disinfector WD test

To be launched in 2018

RAPID PROTEIN SWAB TEST

The Swab test is detecting remaining proteins on instruments by a single swab. A perfect inspection tool to discover whether washed and disinfected instruments still contains any protein residues. A simple swab over the instruments surface leads to an almost instant read-out (a few seconds) whether the instrument contains higher levels of protein.

Detects protein level as from 20 µg. Swab is coloring from yellow to green in case of protein detection. Result in 5 seconds.

906.003.0050 Rapid Protein Swab Test with 50 x 2 tests

Unit: 100 pieces



CONTAINER CARD

Container cards are an important aid to label and mark the container. Not only the content but also details like Sterilization date, Expiry date, the person who packed the container can be written down on the card. The chemical process indicator Type 1 is giving the indication whether it has been sterilized or not. The container card can be used for keeping records at the operating room when it is stored in the patient record.

Characteristics:

- Dimensions: 68 x 37,5 mm.
- Suitable for steam sterilization processes.
- Can be fully recycled.
- Steam indicator conform to ISO 11140 - Type 1
- Clear color transition of the indicator

903.101.0250 Container card Unit : 250 pieces



CONTAINER FILTER

The **Sterintech™** Container Filter is based upon both standards ISO 11607 and ISO 11140 and compliant to those standards. The used materials are mechanically strong to withstand the vacuum and steam pulse movements and are an effective biological barrier.

Characteristics:

- Medical grade paper, 60 gram per square meter.
- In accordance with ISO 11607 - 1 : Hydrophobic, for containers
- High mechanical strength and low liquid permeability
- Steam indicator conform to ISO 11140 - Type 1
- Clear color transition of the indicator (Yellow - Dark)
- Contains no toxic materials

901.101.1000 Container filter round, indicator middle

Unit : 500 pieces

901.102.1000 Container filter round, indicator at lash

Unit : 500 pieces

CONTAINER SEAL

In order to secure the container for opening by un-authorized staff the container seals are offering an important shackle in the quality management chain. Prevents opening by un-authorized staff. Only by breaking the seal the container can be opened. A check at the OR for broken seals is guaranteeing the sterility of materials from the moment of sterilization till the actual use.

Characteristics:

- Produced in polypropylene, softening above 150°C.
- Suitable for steam sterilization processes.
- Fulfilling EN 868 part 8 section 4.2.3
- Can be fully recycled.
- Steam indicator conform to ISO 11140 - Type 1
- Clear color transition of the indicator

902.101.1000 Container seal, Plastic, blue Unit : 1000 pieces

902.102.1000 Container seal, Plastic, blue+indicator Violet - Green Unit : 1000 pieces

902.103.1000 Container seal, Plastic, red Unit : 1000 pieces

902.104.1000 Container seal, Plastic, red, indicator Violet - Green Unit : 1000 pieces





SELF - ADHESIVE CONTAINER SEAL

This Container seal offers a few advantages above the plastic container seals i.e.

- Can be used to glue into patient records.
- No plastic waste

Characteristics:

- Produced from 180 gr/sqm paper.
- Suitable for steam sterilization processes.
- Fulfilling EN 868 part 8 section 4.2.3
- Can be fully recycled.
- Steam indicator conform to ISO 11140 - Type 1
- Clear color transition of the indicator

902.105.1100 Container seal, paper with pin Violet - Green

Unit : 1100 pieces

INSTRUMENT - FIX

The Steritech™ Instrument-Fix are designed to hold sharp instruments like scissors, needles, pincers etc. and are having a triple function: Fixate sharp edged instruments and scissors and protecting the sterile barrier (pouch) from the sharp edge to puncture the film or paper of the sterile barrier. In doing so it helps maintain the sterile integrity of Medical Devices and their packaging.

Protecting the sharp edges of the instruments from being damaged during processing

The Instrument-Fix medium is especially designed to hold and fixate scissors in an opened position in order that the sterilant can reach the sharp surfaces easily.

The Instrument-Fix is a high grade white paper in which holes are provided for as well as a plastic pouch at the bottom in which the sharp part of the instrument is being place in.

The Instrument-Fix are designed for Steam, Formaldehyde and Ethylene-Oxide sterilization. They are not suitable for plasma sterilization purposes.

Steam cycle parameter may range from 121°C - 15 minutes up to 134°C with a maximum of 18 minutes.

905.201.0100	Instrument fix - Small	Blue - Pink	Unit : 100 pieces
905.202.0100	Instrument fix - Medium	Blue - Pink	Unit : 100 pieces
905.203.0100	Instrument fix - Large	Blue - Pink	Unit : 100 pieces
905.204.0100	Instrument fix - X-Large	Blue - Pink	Unit : 100 pieces



CSSD MARKERS

The Steritech™ CSSD Markers are very suitable to be used for CSSD applications. These non toxic markers are coming in four different colors and have a fine tip to create a clear writing possible on various substrates. The writings by these markings are not disappearing during any kind of sterilization method.

Characteristics:

- Available in 4 colors, permanent markers with pocket clip
- Very fine point in order to create clear writings
- No leaking, fast drying, water resistant
- Not blurring during sterilization (depending of absorbance of paper)
- Non-toxic - safe to use - easy disposal
- Shelf-Life: 2 years after production date

905.101.0006	Sterimarker, non toxic	Blue	Unit : 6 pieces
905.102.0006	Sterimarker, non toxic	Red	Unit : 6 pieces
905.103.0006	Sterimarker, non toxic	Green	Unit : 6 pieces
905.104.0006	Sterimarker, non toxic	Black	Unit : 6 pieces



STICKY MATS

The **Sterintech™** Sticky mats are used to place on the floor at entries of CSSD or other clean or sterile areas. They serve to get dust and small particles from the bottom of shoes / slippers / clogs. They consist of multi-layered sticky materials which can be peeled-off one after the other depending on how dirty they have become.

The Sterintech™ Sticky Mats materials are characterized by the following:

- Ruggedized layers.
- Water repellent
- Can serve as Infection prevention measure
- High resistance to tearing
- High stickiness to ensure small particles and dust are stuck to the sticky mats.

908.101.0030	Sticky Mat 1	30 peel-able sheets	45x115 cm	Unit : 1 pieces
908.101.0040	Sticky Mat 2	40 peel-able sheets	45x115 cm	Unit : 1 pieces
908.102.0030	Sticky Mat 3	30 peel-able sheets	65x115 cm	Unit : 1 pieces
908.103.0030	Sticky Mat 4	30 peel-able sheets	92x153 cm	Unit : 1 pieces



WATER - SOLUBLE BAG

The **Sterintech™** Water soluble bags are used to collect contaminated laundry and to transport them safely to the washing area where they can be placed inside the washer without opening the bag. Risk of contamination is reduced dramatically as result.

Today Infection control is getting increasingly important since more and more bacteria starts to get resistant to the latest antibiotics. Infection Prevention is the key word.

The Sterintech™ Water soluble bags are characterized by the following:

- Water soluble film upon 60 degrees Celsius.
- Clear translucent film
- Can serve as Infection prevention measure
- 1,25 gram / cm³ at 20 degrees Celsius

908.260.0100	Water soluble bag, 20 um, hot	4 rolls each 25 bags	Unit : 100 pieces
908.240.0100	Water soluble bag, 20 um, col	4 rolls each 25 bags	Unit : 100 pieces

Seal Checker

The ISO 11607 - 2 is describing the IQ, OQ and PQ procedures which are applicable to Medical Packaging / Sterile barrier systems.

For Operational Qualification (OQ) and daily testing of your heat sealing device in accordance with EN ISO 11607-2 the Sterintech™ Seal Checker can be used as a indicator placed in between the layers of Medical pouches and seal it. By its unique printed pattern of the black area the inspection of the seal and the detection of minor or bigger problems are easily detected.

Guidelines of the DGSV and WFHSS are advising to test each Medical heat sealer at the beginning of the day after the heat sealer has heated up. Based upon the initial test the heat sealer can be released for the day.

The **Sterintech™** Seal Checker is a perfect aid in testing the Medical heat sealer and to record the test data for each machine and each day.

The Seal Checker is used as a sheet which is placed in between the layers of a medical pouch with the face up to the laminate side of the pouch. The combination is then heat sealed after which one can read the test results quite easily.

As such the Seal Checker can display the following heat sealer problems:

- Sealing temperature too low
- Sealing pressure too low
- Interruptions in the seal

909.001.0250	Seal Checker	Unit: 250 pieces
--------------	--------------	------------------





SP Medikal San. Ltd. Şti. / SP International Sağlık Ltd. Şti.

Topçular Mah. Rami Kışla Cad.
Altındağ İş Merkezi No: 63/1-2
Rami/ Eyüp - İSTANBUL - TURKEY

Tel: +90 212 613 80 54
Fax: +90 212 613 80 55

Email: info@spmedikal.com
Web: www.spmedikal.com

 /spmedikal

