

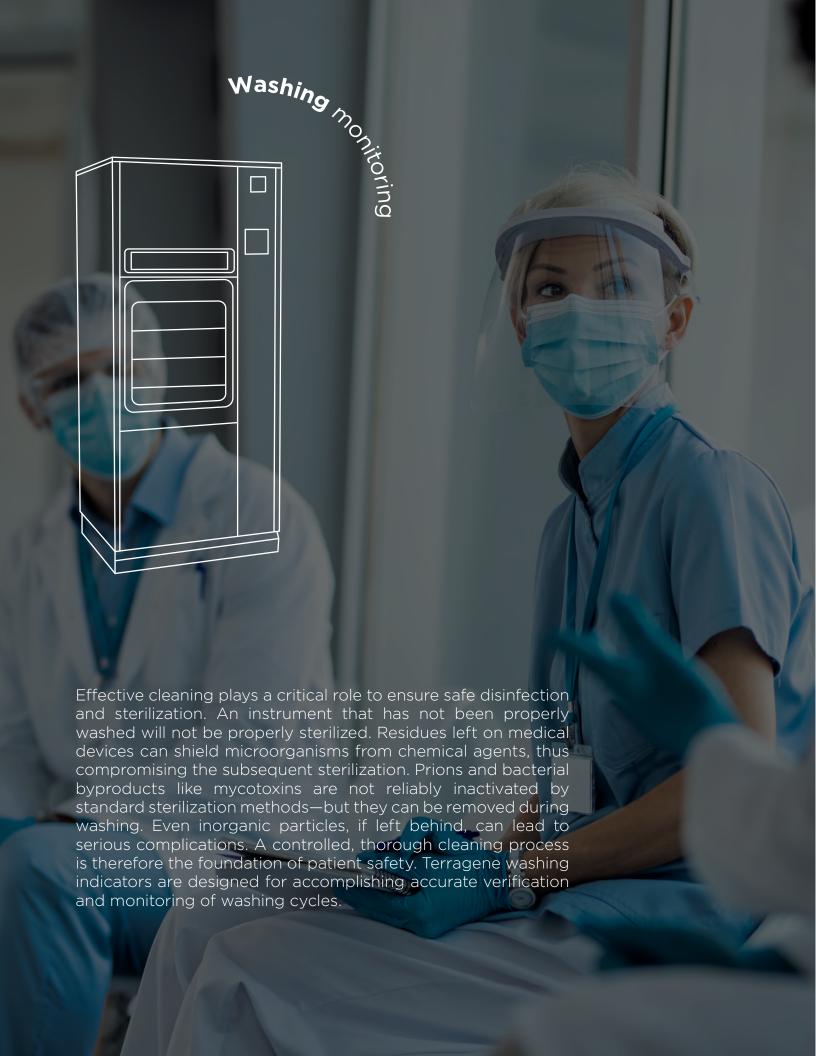
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# **Cleaning** monitoring

- → Washing
- → Disinfection
- → Endoscope reprocessing







#### For ultrasonic cleaning

Precision-engineered for seamless control and monitoring, enhancing the effectiveness of ultrasonic cavitation process.

Indicator for ultrasonic cavitation performance

SKU: CDWU-Z Brand: Chemdye®

Category: Washing control

Process: Cleaning Initial color:

Cavitation failures: 
Correct cavitation:

**Conditions:** Frequencies ≥ 35 kHz, from 18 °C to 70 °C

Related products:





Optimal cleaning with Splat Indicators: Designed to monitor every parameter of your ultrasonic washing process.

Splat washing indicator + Holder for ultrasonic washers

SKU: CDWA4 Brand: Chemdye®

Category: Washing control

Process: Cleaning Initial color:

Final color: ○ (no test soil residues)
Conditions: frequencies ≥ 35 kHz, from

30 °C to 70 °C.

Challenge level: Very high

SKU: CDWA3 Brand: Chemdye®

Category: Washing control

Process: Cleaning Initial color:

Final color: ○ (no test soil residues)
Conditions: frequencies ≥ 35 kHz, from

30 °C to 70 °C.

Challenge level: High









**Related products:** 







#### For thermal-disinfection washers

Optimal cleaning with Splat Indicators: Engineered for comprehensive parameter monitoring in your washer-disinfectors

Splat washing indicator + Holder for thermal-disinfection washers

SKU: CDWA4 Brand: Chemdye®

Category: Washing control

Process: Cleaning Initial color:

**Final color:** ○ (no test soil residues) **Conditions:** temperature >50°C,

time >5 minutes.

Challenge level: Very high





**SKU:** CDWA3 **Brand:** Chemdye®

Category: Washing control

Process: Cleaning Initial color:

**Final color:** ○ (no test soil residues) **Conditions:** temperature >40°C,

time >3 minutes. **Challenge level:** High





#### **Related products:**









#### Thermodisinfection Indicators for moist heat disinfection

SKU: IT27W-1 Brand: Integron®

**Category:** Thermodisinfection

**Process:** Moist heat disinfection processes in washer disinfectors

Initial color: Final color:

**Emulation condition:** 1 min at 90 °C. or  $A_0 = 600$ 



**SKU:** IT27W-5 **Brand:** Integron®

Category: Thermodisinfection

**Process:** Moist heat disinfection processes in washer disinfectors

Initial color: Final color:

**Emulation condition:** 5 min at 90 °C. or  $A_0 = 3000$ .



SKU: IT27W-10 Brand: Integron®

**Category:** Thermodisinfection

**Process:** Moist heat disinfection processes in washer disinfectors

Initial color: Final color:

Emulation condition: 10 min at 93 °C (BGA/RKI/EPIDEMIC

PROGRAM) or equivalent.



#### **Related products:**











#### Cleaning monitoring | Endoscope Reprocessing

Challenge Kits designed for monitoring the effectiveness of internal channel as well as external surface cleaning performance.

Brand: Chemdye®

**Category:** Cleaning monitoring **Process:** Endoscope reprocessing

Initial color:

**Final color:** (no test soil residues)





#### **Related products:**



KPRO2-E250 Qualitative Hygiene monitoring system for cannulated devices



# Hygiene monitoring

→ Residual protein detection







# Don't just clean, verify. Meet the hygiene standard: accurate protein quantification for optimal hygiene monitoring.

Designed to detect and quantify proteins with high sensitivity on surfaces and difficult-to-access areas after the cleaning process

**SKU:** PRO1 MICRO **Brand:** Chemdye®

Category: Hygiene monitoring

**Readout time:** 4 minutes at 60°C with MiniPro and 7 minutes with IC10/20FR or IC10/20FRLCD

Limit of quantification: 1.0 µg of BSA

**Sensitivity:** 0.3µg of BSA **Compatible devices:** 









Designed to verify the cleanliness of cannulated instruments, such as endoscopes, by detecting and quantifying protein residues in their internal channels.

**SKU:** PRO1 ENDO + SWE Swabs

Brand: Chemdye®

Category: Hygiene monitoring

**Readout time:** 4 minutes at 60°C with MiniPro and 7 minutes with IC10/20FR or IC10/20FRLCD

Limit of quantification: 1.0  $\mu g$  of BSA

Sensitivity: 0.5µg of BSA

→2.5 m swabs, available in 4 diameters:









#### Compatible devices:













# Comply with hygiene standards through advanced hygiene monitoring.

Designed to detect proteins in endoscopes and other reusable instruments with hard to reach internal channels or cannulated instruments.

**SKU:** KPRO2-E250 **Brand:** Chemdye®

Category: Hygiene monitoring

Readout time: 1 minute at room temperature

Minimum detection: 1µg



Designed to detect proteins on surfaces of surgical equipment after the cleaning process and in hard to reach areas.

SKU: KPRO2-E69 Brand: Chemdye®

Category: Hygiene monitoring

Readout time: 1 minute at room temperature

Minimum detection: 1µg



# Sterilization monitoring

- → Steam
- → Hydrogen peroxide
- ⇒ Ethylene oxide
- → Formaldehyde
- → Dry heat



Steam sterilization processes are the leading methods used in healthcare to safely and reliably eliminate all forms of microbial life, including highly resistant bacterial spores. Using saturated steam under pressure, this method ensures penetration and heat transfer, denaturing proteins and destroying microorganisms. Its non-toxic nature and reliability make it ideal for heat- and moisture-tolerant medical instruments.

Successful steam sterilization depends on time, temperature and saturated steam, but also on air removal, direct steam contact, and drying. Terragene offers a comprehensive range of validated chemical indicators to monitor these parameters and biological indicators to ensure letality and effectiveness of the process. Designed for compliance and performance, our solutions support high-level infection control across the entire sterilization workflow.

#### Variables to monitor













#### Type 1 Self-adhesive indicator tape for steam

SKU: CT22 Brand: Cintape®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

**→ FDA-cleared** 



#### Type 1 Self-adhesive label indicator for automatic labeler

SKU: CD23

Brand: Chemdye®

**Category:** Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

Compatible devices:





#### Type 1 Double adhesive labels for data registration

SKU: CD28

Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.







## Reliable pre-assembled packages for Bowie-Dick test evaluation.

Type 2 Bowie-Dick Test Pack for testing air removal efficiency of vacuum-assisted steam sterilizers.

SKU: BD125X/2 Brand: Chemdye®

**Category:** Chemical Indicators

Process: Steam Initial color: • Final color: •

Indicator type: Type 2 Chemical Indicator

**Conditions:** 16.9 minutes at 121 °C | 4 minutes at 132 °C |

3.5 minutes at 134 °C

**Compliance:** ISO 11140-1:2014 and ISO 11140-4:2014. EN 285. → Simulates the 7 kg handmade pack described in EN 285.



SKU: BD125X/1 Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

Indicator type: Type 2 Chemical Indicator

**Conditions:** 4 minutes at 132 °C | 3.5 minutes at 134 °C **Compliance:** ISO 11140-1:2014 and ISO 11140-5:2014.

ANSI/AAMI ST79:2017.

 $\rightarrow$  Includes an early warning sheet for proactive sterilization control

#### **→ FDA-cleared**

→ Simulates the 4 kg handmade pack described in ANSI/AAMI ST79:2017.







#### Bowie-Dick Test Card chemical indicators + Holder

### Type 2 Bowie-Dick Test Card Kit for testing air removal efficiency of vacuum-assisted steam sterilizers

**SKU:** KBD8948X **Brand:** Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 2 Chemical Indicator

**Conditions:** 4 minutes at 132 °C | 3.5 minutes at 134 °C. **Compliance:** ISO 11140-1:2014 and ISO 11140-4:2014. EN 285. → Simulates the 7 kg handmade pack described in EN 285.



SKU: KBD8948X/1 Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

Indicator type: Type 2 Chemical Indicator

**Conditions:** 4 minutes at 132 °C | 3.5 minutes at 134 °C. **Compliance:** ISO 11140-1:2014 and ISO 11140-5:2014.

ANSI/AAMI ST79:2017.

 $\hookrightarrow$  FDA-cleared

→ Simulates the 4 kg handmade pack described in

ANSI/AAMI ST79:2017.







# Helix-PCD + Test strips Kit for Steam sterilization processes

Type 2 Helix-PCD (1.5 meters) + Bowie & Dick simulation test strips Kit for monitoring vacuum-assisted steam sterilizers

**SKU:** KH2X15-3.5BD/P **Brand:** Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: 
Final color:

**Indicator type:** Type 2 Chemical Indicator

Conditions: Bowie & Dick cycle: 3.5 minutes at 134 °C.

**Compliance:** ISO 11140-1:2014.



#### Type 2 Helix-PCD (1.5 meters) + Chemical Indicator test strips Kit

SKU: KH2X15-3.5Y/P Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

Indicator type: Type 2 Chemical Indicator

Conditions: 3.5 min at 134 °C Compliance: ISO 11140-1:2014.

SKU: KH2X15-5.3Y/P Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 2 Chemical Indicator

Conditions: 5.3 minutes at 134 °C | 15 minutes at 121 °C.

Compliance: ISO 11140-1:2014.

**SKU:** KH2X15-7.0Y/P **Brand:** Chemdye®

**Category:** Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 2 Chemical Indicator

Conditions: 7 minutes at 134°C | 20 minutes at 121 °C.

**Compliance:** ISO 11140-1:2014.











#### Type 4 Multivariable chemical indicator for steam

SKU: CD29

Brand: Chemdye®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

Indicator type: Type 4 Chemical Indicator

**Conditions:** 121 to 135 °C **Compliance:** ISO 11140-1:2014.

→ FDA-cleared



#### Type 5 Moving front Integrator for steam

SKU: IT26-C | IT26-C EXTENDER

Brand: Integron®

Category: Chemical Indicators

Process: Steam

Indicator type: Type 5 Chemical Indicator

Conditions: 118 to 138 °C. Compliance: ISO 11140-1:2014.

**⇒ FDA-cleared** 



#### Type 5 Chemical Integrator for steam

SKU: IT26-1YS
Brand: Integron®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 5 Chemical Indicator

**Conditions:** 121 to 135 °C **Compliance:** ISO 11140-1:2014.

**→ FDA-cleared** 







#### Type 6 Three Point Emulator indicator for steam

**SKU:** IT28

Brand: Integron®

Category: Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 6 Chemical Indicator

Conditions: 3.5 minutes at 134 °C | 15 minutes at 121 °C

**Compliance:** ISO 11140-1:2014.



#### Type 6 Emulator Indicators for steam

Brand: Integron®

**Category:** Chemical Indicators

Process: Steam Initial color: • Final color: •

**Indicator type:** Type 6 Chemical Indicator

**Compliance:** ISO 11140-1:2014.



SKU	CONDITIONS
IT27-3YS	3 minutes at 134 °C
IT27-4YS	4 minutes at 134 °C   12 minutes at 121 °C.
IT27-5YS	5 minutes at 134 °C   15 minutes at 121 °C
IT27-7YS	7 minutes at 134 °C   20 minutes at 121 °C
IT27-18YS	18 minutes at 134 °C





Accelerate sterility assurance with fluorescence indicators for fast, reliable results when time matters.

#### 7 seconds Biological Indicator for steam

SKU: BT225 Brand: Bionova®

Category: Biological Indicators, Instant Fluorescence

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Conditions:** 132 to 135 °C

Readout time: 7 seconds at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

→ High sensitivity→ FDA-grantedCompatible devices:





#### 20 minutes Biological Indicator for steam

SKU: BT224
Brand: Bionova®

Category: Biological Indicators, Rapid Fluorescence

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Conditions:** 132 to 135 °C

Readout time: 20 minutes at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.













#### 1 hour Biological Indicator for steam

SKU: BT222 Brand: Bionova®

Category: Biological Indicators, Rapid Fluorescence

**Process:** Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Conditions:** 121 to 135 °C **Readout time:** 1 hour at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

→ FDA-cleared Compatible devices:









#### 3 hours Biological Indicator for steam

SKU: BT220 Brand: Bionova®

Category: Biological Indicators, Rapid Fluorescence

**Process:** Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Conditions:** 121 to 135 °C **Readout time:** 3 hours at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.













# Comprehensive Steam Sterilization Testing for Maximum Safety.

#### 7 seconds Test Pack Process Challenge Device

**SKU:** KPCD225-2 | KPCD225-C

Brand: Bionova®

Category: Process Challenge Device

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 10<sup>6</sup> Spores/carrier Conditions: 132 to 135 °C

Readout time: 7 seconds at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

ISO 11140-1:2014. ANSI/AAMI ST79.

→ FDA-clearedCompatible devices:







#### 20 minutes Test Pack Process Challenge Device

SKU: KPCD224-2 | KPCD224-C

Brand: Bionova®

Category: Process Challenge Device

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 10<sup>6</sup> Spores/carrier Conditions: 132 to 135 °C

Readout time: 20 minutes at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

ISO 11140-1:2014. ANSI/AAMI ST79.















#### 1 hour Test Pack Process Challenge Device

SKU: KPCD222-2 | KPCD222-C

Brand: Bionova®

Category: Process Challenge Device

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 10° Spores/carrier Conditions: 121 to 135 °C Readout time: 1 hour at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

ISO 11140-1:2014. ANSI/AAMI ST79.

→ FDA-clearedCompatible devices:











#### 3 hours Test Pack Process Challenge Device

SKU: KPCD220-2 | KPCD220-C

Brand: Bionova®

Category: Process Challenge Device

Process: Steam

Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 10<sup>6</sup> Spores/carrier Conditions: 121 to 135 °C

Readout time: 3 hours at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

ISO 11140-1:2014. ANSI/AAMI ST79.















With Biological Indicators, the lethality of the sterilization cycle can be assessed with direct microbiological inactivation, ensuring maximum safety in the process.

#### 24 hours Biological Indicator for steam

SKU: BT20 Brand: Bionova®

Category: Biological Indicators, Conventional Self-Contained

Process: Steam

**Microorganism:** Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Conditions:** 121 to 135 °C

Readout time: 24 hours at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-3:2017.

**Compatible devices:** 











#### Sterilization monitoring | Hydrogen peroxide

## Type 1 Self-adhesive indicator tape for hydrogen peroxide

SKU: CT40 Brand: Cintape®

**Category:** Chemical Indicators **Process:** Hydrogen peroxide

Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

→ FDA-cleared



## Type 1 Self-adhesive label indicator for hydrogen peroxide

SKU: CD43

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Hydrogen peroxide

Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

**Compatible devices:** 





Type 1 Documentation System labels. Double adhesive labels printed with indicator ink for data registration.

**SKU:** CD48

**Brand:** Chemdye® **Category:** Chemical Indicators

**Process:** Hydrogen peroxide

Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.







## Type 1 Process indicator for hydrogen peroxide

SKU: CD42

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Hydrogen peroxide

Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

→ FDA-cleared



## Type 4 Multivariable indicator for hydrogen peroxide

**SKU:** CD40

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Hydrogen peroxide

Initial color: • Final color: •

Indicator type: Type 4 Chemical Indicator

Compliance: ISO 11140-1:2014.

→ FDA-cleared



## Type 2 Helix-PCD + Test strips Kit for hydrogen peroxide sterilization processes.

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Hydrogen peroxide

Initial color: 
Final color:

Indicator type: Type 2 Chemical Indicator

**Compliance:** ISO 11140-1:2014.



#### SKU CHARACTERISTICS

KH2X025-P1/P 0.25 meters length | 2 mm internal diameter

KH2X12-P1/P 1.20 meters length | 2 mm internal diameter





#### Sterilization monitoring | Hydrogen peroxide

# Achieve fast and reliable results with our Biological Monitoring System for H2O2 sterilization processes.

## 5 minutes Biological Indicator for hydrogen peroxide

SKU: BT98
Brand: Bionova®

Category: Biological Indicators, Rapid

Fluorescence

Process: Hydrogen peroxide
Microorganism: Geobacillus
stearothermophilus ATCC® 7953
Population: 106 Spores/carrier
Readout time: 5 minutes at 60 °C
Compliance: ISO 11138-1:2017.

→ FDA-clearedCompatible devices:





## **30 minutes** Biological Indicator for hydrogen peroxide

SKU: BT96 Brand: Bionova®

Category: Biological Indicators, Rapid

Fluorescence

Process: Hydrogen peroxide Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 10<sup>6</sup> Spores/carrier Readout time: 30 minutes at 60 °C

Compliance: ISO 11138-1:2017. → FDA-cleared



MiniBio

Auto-







## **24 hours** Biological Indicator for hydrogen peroxide

SKU: BT91 Brand: Bionova®

Category: Biological Indicators, Conventional Self-Contained Process: Hydrogen peroxide Microorganism: Geobacillus stearothermophilus ATCC® 7953 Population: 106 Spores/carrier Readout time: 24 hours at 60 °C Compliance: ISO 11138-1:2017.

**Compatible devices:** 







Ethylene oxide (EO) sterilization is a widely used method for reprocessing medical devices that are sensitive to heat and moisture. As a potent alkylating agent, EO disrupts the molecular structure of microorganisms, impairing their metabolic and reproductive functions, and ultimately leading to cell death. Its ability to penetrate packaging and complex lumens makes it ideal for a broad range of healthcare products that can't be sterilized at high temperatures.

The process relies on four critical parameters: exposure time, temperature, humidity, and EO concentration. Terragene offers a complete range of chemical and biological indicators, specifically designed following ISO standards, to monitor and validate EO sterilization cycles. Our solutions ensure consistent performance and compliance in the most demanding sterilization environments.

#### Variables to monitor













## Type 1 Self-adhesive indicator tape for ethylene oxide

SKU: CT10 Brand: Cintape®

**Category:** Chemical Indicators **Process:** Ethylene oxide

Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.



#### Type 1 Self-adhesive label indicator for automatic labeler

SKU: CD13

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Ethylene oxide

Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

**Compatible devices:** 





#### Type 4 Multivariable chemical indicator

SKU: CD16

Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Ethylene oxide

Initial color: • Final color: •

Indicator type: Type 4 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

 $\hookrightarrow$  FDA-cleared







## Two-level integrator to ensure correct and safe conditions inside the package.

#### Type 5 Chemical Integrator for EO

**SKU:** IT12

Brand: Integron®

Category: Chemical Indicators

**Process:** Ethylene oxide

Indicator type: Type 5 Chemical Indicator

Compliance: ISO 11140-1:2014.

→ FDA-cleared



# Self-contained Biological Indicators for easy and safe evaluation of process lethality.

#### 4 hours Biological Indicator for EO

SKU: BT110 Brand: Bionova®

Category: Biological Indicators, Rapid Fluorescence

Process: Ethylene oxide

Microorganism: Bacillus atrophaeus ATCC® 9372

**Population:** 10<sup>6</sup> Spores/carrier **Readout time:** 4 hours at 37 °C **Compliance:** ISO 11138-1:2017 and

ISO 11138-2:2017.

→ FDA-cleared

Compatible devices:









#### 48 hours Biological Indicator for EO

SKU: BT10
Brand: Bionova®

Category: Biological Indicators, Conventional Self-Contained

Process: Ethylene oxide

Microorganism: Bacillus atrophaeus ATCC® 9372

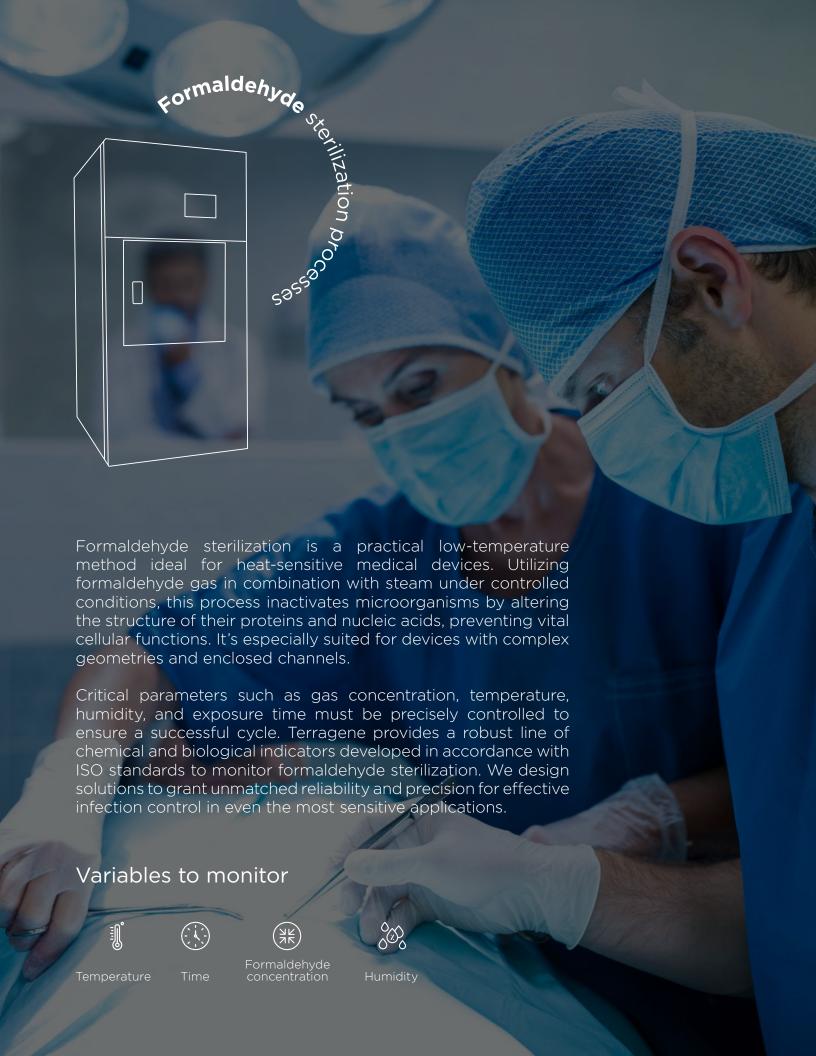
**Population:** 10<sup>6</sup> Spores/carrier **Readout time:** 48 hours at 37 °C **Compliance:** ISO 11138-1:2017 and

ISO 11138-2:2017.

Compatible devices:











## Type 1 Self-adhesive indicator tape for formaldehyde

SKU: CT50 Brand: Cintape®

**Category:** Chemical Indicators

Process: Formaldehyde

Initial color: • Final color: •

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.



## Type 1 Self-adhesive label indicator for formaldehyde

**SKU:** CD53

Brand: Chemdye®

Category: Chemical Indicators

Process: Formaldehyde

Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.

Compatible devices:





## Type 2 Helix-PCD (1.5 meters) + Test strips Kit for Formaldehyde sterilization processes.

SKU: KH2X15-F1 Brand: Chemdye®

**Category:** Chemical Indicators **Process:** Formaldehyde

Initial color: • Final color: •

**Indicator type:** Type 2 Chemical Indicator

**Compliance:** ISO 11140-1:2014.







Type 4 Multivariable indicators that confirm the proper penetration of the sterilizing agent into the package.

SKU: CD50 Brand: Chemdye®

Category: Chemical Indicators

Process: Formaldehyde

Initial color: • Final color: •

Indicator type: Type 4 Chemical Indicator

Compliance: ISO 11140-1:2014.



## Achieve fast and reliable results with our Biological Monitoring System for sterilization processes.

#### 2 hours Biological Indicator for formaldehyde

SKU: BT102
Brand: Bionova®

Category: Biological Indicators, Rapid Fluorescence

Process: Formaldehyde

Microorganism: Geobacillus stearothermophilus ATCC® 7953

**Population:** 10<sup>6</sup> Spores/carrier **Readout time:** 2 hours at 60 °C

Compliance: ISO 11138-1:2017 and ISO 11138-5:2017.

Compatible devices:











Dry heat sterilization processes are used in healthcare facilities, especially for items that cannot withstand moisture or steam. Ideal for materials such as powders, oils, vaseline and parafine, this method ensures effective sterilization without compromising the integrity of heat-resistant products.

Since dry heat cycles operate at higher temperatures and longer exposure times, precise monitoring is essential to guarantee sterility assurance. Choosing the right indicators, tailored to cycle temperature, is key to validate the process and ensure patient safety.

Terragene offers high-performance monitoring solutions to support safe and effective dry heat sterilization in every healthcare setting.

#### Variables to monitor









## Reliable tracking starts with our labels — they adhere flawlessly to all types of packs and pouches.

Type 1 Self-adhesive indicator tape for dry heat

SKU: CT30 Brand: Cintape®

Category: Chemical Indicators

Process: Dry heat Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

**Compliance:** ISO 11140-1:2014.



Type 1 Self-adhesive label indicator for automatic labeler

SKU: CD33

Brand: Chemdye®

Category: Chemical Indicators

Process: Dry heat Initial color: 
Final color:

**Indicator type:** Type 1 Chemical Indicator

Compliance: ISO 11140-1:2014.

Compatible devices:





Multivariable indicators for dry heat sterilization: they react within the loads to ensure precise temperature control over time.

Type 4 Multivariable chemical indicator for dry heat

SKU: CD30 Brand: Chemdye®

Category: Chemical Indicators

Process: Dry heat Initial color: 
Final color:

Indicator type: Type 4 Chemical Indicator

**Compliance:** ISO 11140-1:2014.







## Emulator indicator for dry heat sterilization processes.

#### Type 6 Emulator Indicator for dry heat

**SKU:** IT31

Brand: Integron®

Category: Chemical Indicators

Process: Dry heat Initial color: 
Final color:

Indicator type: Type 6 Chemical Indicator

Conditions: 40 minutes at 160 °C Compliance: ISO 11140-1:2014.



# Verify process lethality with our semi self-contained biological indicator for dry heat

48 hours Semi self-contained Biological Indicator for reliable dry heat sterilization monitoring.

SKU: BT30 Brand: Bionova®

Category: Biological Indicators, Conventional Self-contained

Process: Dry heat

Microorganism: Bacillus atrophaeus ATCC® 9372

**Population:** 10<sup>6</sup> Spores/carrier **Readout time:** 48 hours at 37 °C **Conditions:** 160 to 180 °C

Compliance: ISO 11138-1:2017 and ISO 11138-4:2017.

**Compatible devices:** 

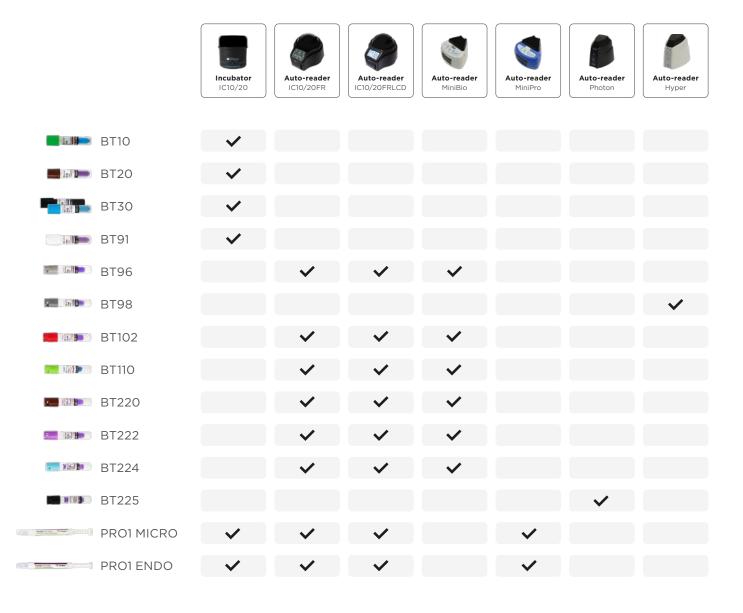






# Compatible devices

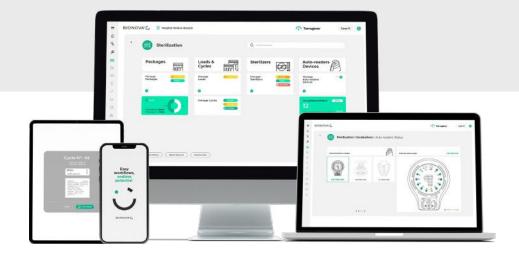
### chart



# Devices & digital tools



Terragene solution for streamlining process monitoring in the CSSD



### No delays, no miscommunication, just clean, connected data



Multiple users, multiple shifts, countless cycles. Without a unified system, critical information can be missed. Bionova Q synchronizes all sterilization data in real time, allowing staff to work in parallel without bottlenecks or delays. Whether it's 2 a.m. or mid-shift, results are updated instantly, removing the risk of miscommunication and enabling smarter, faster decisions.

#### Beyond the CSSD: true clinical integration



Sterilization safety doesn't stop at the department door. Indicators used in the OR also need to be tracked. Bionova Q extends traceability beyond the CSSD, linking test results with procedures, instruments, and even patients when protocols require it. This level of integration transforms sterilization from a support task into a key component of clinical care quality.

### Traceability that follows every step, and every reprocess



Each indicator tells a part of the story — a washing indicator confirms the cleaning process was effective, a protein test confirms hygiene, a chemical indicator confirms sterilization parameters were met, and a biological indicator validates sterilization lethality. But without connection, those insights remain isolated and incomplete. Bionova Q links each result not only to its process, load, and operator, but also to the full history of the reprocessed material, cycle after cycle.

#### Every instrument carries a digital history



The software ensures comprehensive documentation of each material's lifecycle, registering every reprocessing step, control checkpoint, responsible operator, equipment utilized, and managing its reception and dispatch via remittance slips, while precisely indicating its storage position within the central sterile repository.



# Boost the management of your Sterile Process Department

Bionova Q App is the perfect complement to the Bionova Q software. Although it is not required to operate the system, its integration elevates traceability and process control to the next level. With its advanced functionalities, it enables the linking of results, optimizes sterile material storage, and enhances the monitoring of washing and sterilization cycles, ensuring greater efficiency and safety.

#### > Result linking

Records washing and chemical indicator results through the integrated Trazanto Lens system.

#### › Material management

Manages the storage of sterile materials within the Central Sterilization Unit, allowing you to register where each package is stored once released and move it within the unit when needed.

#### > Technical support access

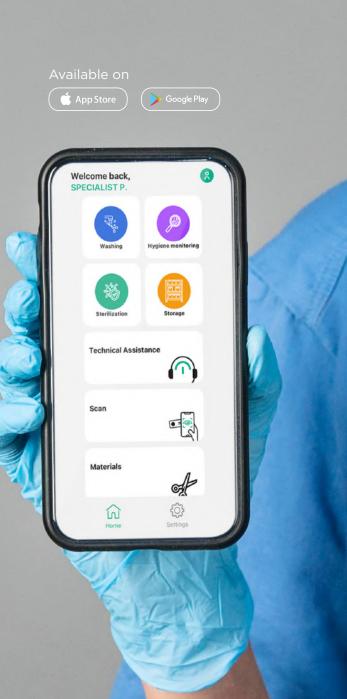
Direct access to the technical assistance application.

#### > Visual documentation

Allows you to upload photos of the materials registered in the Bionova Q system, creating a graphic record of each item.

#### > Cycle monitoring

View all washing and sterilization cycles performed in the central unit.





Achieve automatic quality control for your CSSD/SPD.

This comprehensive and automated quality control software enables disruptive monitoring of washing, hygiene, disinfection, and sterilization processes all at once. Accelerating the workflow leads to better results with less effort.



Automatic data intake



Real-time process KPIs



Information everywhere & anytime

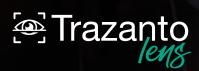


Instant digital reports

Available on

**Windows** 





# Artificial intelligence for infection prevention

Experience the evolution of Trazanto with our state-of-the-art app that enables the reading and digitalization of results to boost workflow efficiency.

A quick scan of washing and chemical indicators ensures efficiency and safety, revolutionizing the way sterile surgical instruments are cleared right before every procedure. Time is life. Move faster!

#### Available on







#### **PORTABILITY**

Improve your workflow with just a mobile phone in CSSD, surgery areas or labs.



#### **COMPLIANCE**

Facilitate audits with easy and quick access to your digital records on Bionova® Cloud.



#### **FAST & SIMPLE**

Fast, intuitive, easy to use, and paperless.



#### **CROSS-INDUSTRY**

Useful and applicable for healthcare, dental and other life sciences areas.

#### THREE SIMPLE STEPS



Go to New scan and take a picture of the washing or chemical indicator



Automatically AI reads the washing or chemical indicator



Done! The report is available on





# Technology, speed, and precision at your fingertips!

Automatic digital detection of your swabbing surfaces, with the ability to estimate the swabbed area, and seamless integration with protein quantification data from Bionova® Auto-readers.

Designed to comply with required ISO 15883-5:2021 thresholds on µg/cm2 units.



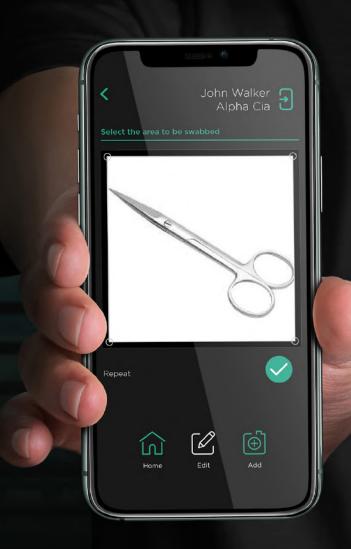
Take a picture of the surface you want to swab. We do the rest.



Automatic detection and standardization of your test surfaces for washing and cleaning processes.



The app complements the use of MiniPro, IC10/20FR and IC10/20FRLCD auto-readers, and PRO1 MICRO swabs.



#### Available on











### Our auto-readers provide the fastest results on the market

Photon Auto-reader for Steam Biological Indicators

SKU: BPH

**Brand:** Bionova®

Working temperature: 60 ± 2 °C

**Characteristics:** 

→ 2 positions to incubate Bionova® BT225 Photon Biological Indicators (7 seconds program). → Virtual ticket generation with Bionova® App

Wireless assistant.

→ Bluetooth/Wi-Fi wireless technology connectivity.

→ High sensitivity **⇒** FDA-granted





Hyper Auto-reader for VH2O2 **Biological Indicators** 

SKU: BHY

Brand: Bionova®

Working temperature:  $60 \pm 2$  °C

**Characteristics:** 

→ 2 positions to incubate Bionova® BT98 Hyper Biological Indicators (5 minutes program). → Virtual ticket generation with Bionova® App

Wireless assistant.

→ Bluetooth/Wi-Fi wireless technology connectivity.

**→ FDA-cleared** 







# Fast, safe, and easy to use: our auto-readers provide quick and accurate results.





SKU: IC10/20FRLCD Brand: Bionova®

**Working temperature:** Dual temperature system:

37 and 60 °C. Allows running different incubation times simultaneously.

#### **Characteristics:**

→ 12 positions to incubate rapid, super rapid and ultra rapid fluorescence readout SCBIs and 1 position to incubate

Protein Pen.

 $\hookrightarrow$  3.5" touch screen LCD. Visual information of the remaining time of the incubation process.

→ Thermal printer of results. Stores 208 results.

→ Ethernet connection for recording results on PC using Bionova®Cloud or Bionova® Q Web Applications.

**⇒ FDA-cleared** 



Fluorescence Auto-reader for Biological Indicators

SKU: IC10/20FR Brand: Bionova®

Working temperature: Dual temperature system:

37 and 60 °C. Allows running different incubation times simultaneously.

#### **Characteristics:**

→ 12 positions to incubate rapid, super rapid and ultra rapid fluorescence readout SCBIs and 1 position to incubate Protein Pen.

→ Stores 50 results. Thermal printing of last 13 results.

→ USB connection for recording results on PC using Bionova® Cloud and Bionova® Q Web Applications.

→ FDA-cleared

<b>TEMP</b> 60°C	TIME 20 min. (Ultra) 30 min. 1 hs 2 hs 3 hs PRO (7 min.)	INCUBATION PROGRAM 20 min. at 60°C 30 min. at 60°C 1 hour at 60°C 2 hours at 60°C 3 hours at 60°C PRO at 60°C
37°C	4 hs	4 hours at 37°C









# Compact, fast, and easy to use: Our auto-readers and incubators offer efficient solutions for both hygiene monitoring systems and BIs readings.

MiniBio Auto-reader for Biological Indicators

SKU: MINIBIO Brand: Bionova®

**Working temperature:** Dual temperature system: Allows selecting between two different incubation temperatures 37 and 60 °C.

#### **Characteristics:**

→ 3 positions to incubate Rapid, Super Rapid, and Ultra Rapid Biological Indicators.

→ Integrated thermal printer.

→ USB connection for recording results on PC using a Readout and Traceability software.

#### **⇒ FDA-cleared**

TEMP 60°C	TIME 20 min. 30 min. 1 hs 2 hs 3 hs	INCUBATION PROGRAM 20 min. at 60°C 30 min. at 60°C 1 hour at 60°C 2 hours at 60°C 3 hours at 60°C
37°C	4 hs	4 hours at 37°C



for Hygiene monitoring system

SKU: MINIPRO Brand: Bionova®

Working temperature: 60 °C. Process: Hygiene Monitoring

**Characteristics:** 

→ 3 positions for incubation and transmittance readout of hygiene indicators.

→ Integrated thermal printer.

→ USB connection for recording results on PC using a Readout and Traceability software.

TEMP	TIME	INCUBATION PROGRAM
60°C	PRO (4 min)	PRO at 60°C

















Dual Incubator for conventional Biological Indicators

SKU: IC10/20 Brand: Bionova®

Working temperature:  $37 \pm 2$  °C,  $60 \pm 2$  °C Characteristics:

→ 26 positions to incubate BI and 10 positions to incubate culture media and protein pen (visual interpretation only).



Manual 3-line labeller with 12 alphanumeric digits in each line.

**SKU:** CG3

Brand: Chemdye®

To use with: CD13, CD23, CD33,

CD43 and CD53 labels.

 $\hookrightarrow$  Works with a replaceable internal ink

roller (IRCG3).





## Products presentation chart

PRODUCT	DESCRIPTION	UNITS/PACKAGING
BD125X/1	Bowie-Dick Test Pack	20 units per box
BD125X/2	Bowie-Dick Test Pack	20 units per box
BHY	Auto-reader for VH2O2 BIs	1 unit per box
BT10	48 h Biological Indicator for EtO	30/100 units per box
BT20	24 h Biological Indicator for steam	30/100 units per box
BT30	48 h Biological Indicator for dry heat	50 units per box: 25 tubes A + 25 tubes B
BT91	24 h Biological Indicator for VH <sub>2</sub> O <sub>2</sub>	100 units per box
BT96	30 min. Biological Indicator for VH <sub>2</sub> O <sub>2</sub>	50 units per box
BT98	5 min. Biological Indicator for VH <sub>2</sub> O <sub>2</sub>	50 units per box
BT102	2h Biological Indicator for LTSF	50 units per box
BT110	4 h Biological Indicator for EtO	50 units per box
BT220	3 h Biological Indicator for steam	50 units per box
BT222	1 h Biological Indicator for steam	50 units per box
BT224	20 min. Biological Indicator for steam	50 units per box
BT225	7 sec. Biological Indicator for steam	50 units per box
ВРН	Auto-reader for Photon BIs	1 unit per box
CD13	Self-adhesive label indicator for EtO	1 roll with 750 labels per foil bag or 12-roll boxes
CD16	Multivariable chemical indicator for EtO	250 strips per aluminium foil bag
CD23	Self-adhesive label indicator for steam	1 roll with 750 labels per foil bag or 12-roll boxes
CD28	Self-adhesive label indicator for steam	1 roll with 1000 labels per bag
CD29	Multivariable chemical indicator for steam	250 double strips per aluminium foil bag
CD30	Multivariable chemical indicator for dry heat	250/500 strips per aluminium foil bag
CD33	Self-adhesive label indicator for dry heat	1 roll with 750 labels per foil bag or 12-roll boxes
CD40	Multivariable indicator for VH <sub>2</sub> O <sub>2</sub>	250/500 strips per aluminium foil bag
CD42	Chemical indicator for VH <sub>2</sub> O <sub>2</sub>	250/500 strips per aluminium foil bag
CD43	Self-adhesive label indicator for VH <sub>2</sub> O <sub>2</sub>	1 roll with 750 labels per foil bag or 12-roll boxes
CD48	Self-adhesive label indicator for VH <sub>2</sub> O <sub>2</sub>	1 roll with 1000 labels per bag
CD50	Multivariable chemical indicator for LTSF	250/500 strips per aluminium foil bag
CD53	Self-adhesive label indicator for LTSF	1 roll with 750 labels per foil bag or 12-roll boxes
CDWA3	Splat Washing indicator	200 units per aluminum foil bag
CDWA4	Splat Washing indicator	200 units per aluminum foil bag
CDWAH	Holder for washing indicators	1 unit per box
CDWAH-U	Holder for ultrasonic washing indicators	1 unit per box
CDWU-Z	Indicator for ultrasonic cavitation performance tests	30 units per box
CDWU-H	Holder for Ultrasonic Cleaning Indicator	10 units per box
CG3	Three line automatic labeler	1 labelling device and 1 ink roller per box
CT10	Self-adhesive indicator tape for EtO	1 roll of 50 m x 18 mm



CT22	Self-adhesive indicator tape for steam	1 roll of 50 m x 18 mm
СТ30	Self-adhesive indicator tape for dry heat	1 roll of 50 m x 18 mm
CT40	Self-adhesive indicator tape for VH <sub>2</sub> O <sub>2</sub>	1 roll of 50 m x 20 mm
CT50	Self-adhesive indicator tape for LTSF	1 roll of 50 m x 18 mm
IC10/20	Dual incubator for Biological Indicators	1 unit per box
IC10/20FR	Auto-reader for Biological Indicators	1 unit per box
IC10/20FRLCD	Touchscreen Auto-reader for Biological Indicators	1 unit per box
IT12	Chemical Integrator for EtO	250 units per aluminum foil bag
IT26-1YS	Chemical Integrator for steam	200 strips per aluminium foil bag
IT26-C	Chemical Integrator for steam	250 units per aluminum foil bag
IT27-3YS	Emulator Indicator for steam	200 units per aluminum foil bag
IT27-4YS	Emulator Indicator for steam	200 units per aluminum foil bag
IT27-5YS	Emulator Indicator for steam	200 units per aluminum foil bag
IT27-7YS	Emulator Indicator for steam	200 units per aluminum foil bag
IT27-18YS	Emulator Indicator for steam	200 units per aluminum foil bag
IT27W-1	Thermodisinfection Indicator for moist heat disinfection	200 units per aluminum foil bag
IT27W-5	Thermodisinfection Indicator for moist heat disinfection	200 units per aluminum foil bag
IT27W-10	Thermodisinfection Indicator for moist heat disinfection	200 units per aluminum foil bag
IT28	3 Point Emulator indicator for steam	250 units per aluminum foil bag
IT31	Emulator Indicator for dry heat	250 units per aluminum foil bag
KBD8948X	Bowie-Dick Test Card Kit for steam	120 test cards + 1 holder per box
KBD8948X/1	Bowie-Dick Test Card Kit for steam	120 test cards + 1 holder per box
KH2X025-P1/P	Helix-PCD + Test strips Kit for VH <sub>2</sub> O <sub>2</sub>	1 plastic device (0.25 m)+ 100 strips PCD-A-P1
KH2X12-P1/P	Helix-PCD + Test strips Kit for VH <sub>2</sub> O <sub>2</sub>	1 plastic device (1.2 m)+ 100 strips PCD-A-P1
KH2X15-3.5BD/P	Bowie-Dick simulation Helix kit	1 plastic device + 1 cotton bag + 250 strips
KH2X15-3.5Y/P	3.5 min Helix kit for steam	1 plastic device + 1 cotton bag + 250 strips
KH2X15-5.3Y/P	5.3 min Helix kit for steam	1 plastic device + 1 cotton bag + 250 strips
KH2X15-7.0Y/P	7 min Helix kit for steam	1 plastic device + 1 cotton bag + 250 strips
KH2X15-F1	Helix kit with test strips for LTSF	1 plastic device + 1 cotton bag + 250 strips
KPCD220-2	3h Steam Test Pack PCD Kit   Single point integrator	Kit with 25 PCDs + 25 SCBIs
KPCD220-C	3h Steam Test Pack PCD Kit   Moving front integrator	Kit with 25 PCDs + 25 SCBIs
KPCD222-2	1h Steam Test Pack PCD Kit   Single point integrator	Kit with 25 PCDs + 25 SCBIs
KPCD222-C	1h Steam Test Pack PCD Kit   Moving front integrator	Kit with 25 PCDs + 25 SCBIs
KPCD224-2	20m Steam Test Pack PCD Kit   Single point integrator	Kit with 25 PCDs + 25 SCBIs
KPCD224-C	20m Steam Test Pack PCD Kit   Moving front integrator	Kit with 25 PCDs + 25 SCBIs
KPCD225-2	7s Steam Test Pack PCD Kit   Single point integrator	Kit with 25 PCDs + 25 SCBIs
KPCD225-C	7s Steam Test Pack PCD Kit   Moving front integrator	Kit with 25 PCDs + 25 SCBIs
KPRO2-E250	Qualitative Hygiene monitoring system for cannulated devices	5 reactive solution tubes + 5 SW250 swabs + 2 moisturizer tubes
KPRO2-E69	Qualitative Hygiene monitoring system for detecting residual protein on surfaces	18 reactive solution tubes + 18 SW69 swabs + 2 moisturizer tubes
LUMENIA L1	Cleaning Challenge Kit for cannulated devices reprocessing	1 Challenge Device + 120 cleaning indicators + 1 input terminal + 1 plastic tweezer



LUMENIA L2	Cleaning Challenge Kit for endoscope reprocessors	1 Challenge Device + 120 cleaning indicators + 1 input terminal + 1 plastic tweezer
LUMENIA L122	Cleaning Challenge Kit for endoscope reprocessors	1 Challenge Device + 360 cleaning indicators + 3 input terminal + 1 plastic tweezer
LSF1	Cleaning Challenge Kit for 6-channel endoscope reprocessors	1 Challenge Device + 720 cleaning indicators + 1 plastic tweezer + 6 blockage test capsules
MINIBIO	Auto-reader for Biological Indicators	1 unit per box
MINIPRO	Auto-reader for Hygiene Monitoring Systems	1 unit per box
PRO1 ENDO	Quantitative Hygiene monitoring system for cannulated devices	20 units per box
PRO1 MICRO	Quantitative Hygiene Monitoring System for instrument surfaces	20/100 units per box
SWE-1.7	PRO1 ENDO swabs - Diameter: 1.7 mm.	5 units per bag
SWE-2.0	PRO1 ENDO swabs - Diameter: 2.0 mm.	5 units per bag
SWE-2.7	PRO1 ENDO swabs - Diameter: 2.7 mm.	5 units per bag
SWE-3.0	PRO1 ENDO swabs - Diameter: 3.0 mm.	5 units per bag

# **OEM**DEVELOPMENT DIVISION

# YOUR BRAND, OUR INNOVATION

At Terragene, we understand that every brand has a unique vision. Our **OEM** (**Original Equipment Manufacturer**) and **Private Label** services provide tailored solutions to elevate your brand with high-quality products. Whether you're looking to develop products under your own brand or need a reliable manufacturing partner, we're here to turn your vision into reality.

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