

# Solutions to guarantee safety in Pharmaceutical Industry



Let's work together to create a better future

### What we do?

At Terragene® we develop and manufacture a vast range of infection prevention products adapted to current technologies, user's guidelines, international and local regulations and market demands.

We offer a range of effective, easy-to-handle products to accurately control cleaning, disinfection, hygiene, and sterilization processes in pharmaceutical industries. Available in a variety of formats, these high-performance control devices provide fast and consistent results for infection control.

### terragene.com



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  Trazento\*

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### **Room Disinfection**

In recent years, there is an increasing consensus that improved cleaning and disinfection of environmental surfaces is needed not only in healthcare environment but also in other places like offices, hotels, means of transportation and other public spaces.

We have developed the most complete and innovative portfolio of products for disinfection monitoring in room and airborne disinfection procedures. Technology developed to certify disinfection in operating rooms also applied to everyday life.



# The First Disinfection Certification System

## The importance of environmental Disinfection

Certifying that any available space for human use is disinfected has become indispensable. That is the reason why we have created the first world disinfection certification digital system.

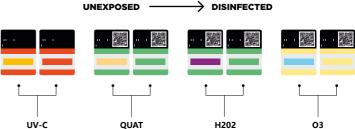
It allows companies to digitize their protocols, systematize and make them visible to their clients for greater trust and security. It is used to plan different protocols in areas with a large influx of people, as hotels, companies, airports, airplanes, cinemas, schools, businesses, means of transportation, gyms, healthcare environments and other kinds of public influx zones.

It uses quality standards similar to those used in operating rooms, but with the simplicity and portability of a mobile APP and the traceability of QR codes, that record level of disinfection in different environments.

Choose between different reactive inks and labels according your own disinfection process: UV-C | Quaternary Ammonium | H202 | O3.

DCS Provides transparent information for companies and customers.

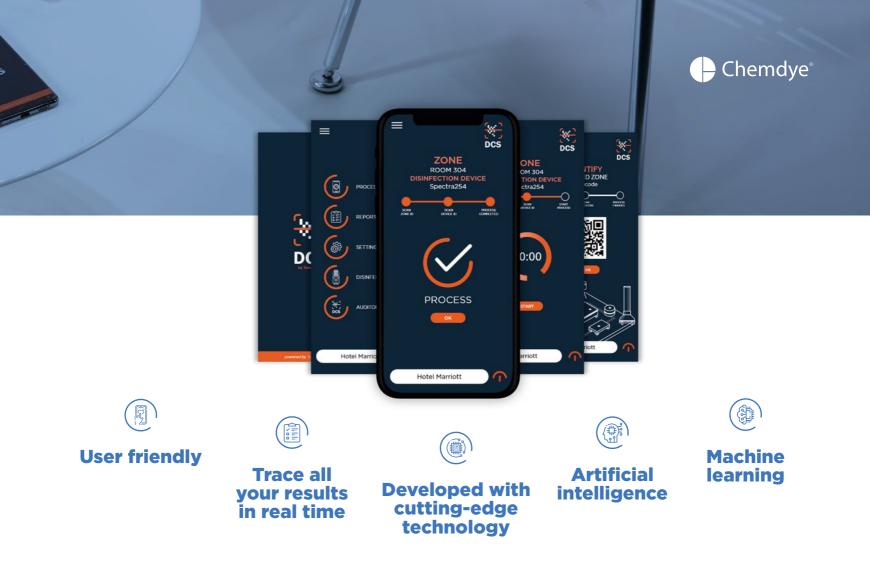




The labels have a QR code that provides the information of a specific place that has been disinfected.







This application was developed in order for organizations to trace their disinfection control processes and gain access to the DCS Certification.

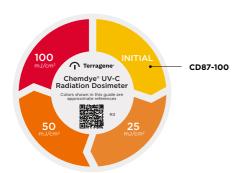
It allows companies to digitize their disinfection protocols, that lets the user check the disinfection status, which will be interpreted using concepts of Artificial Intelligence.

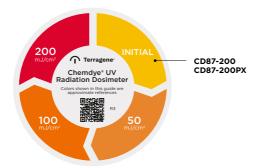


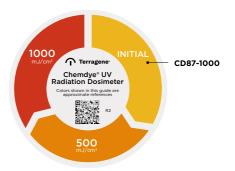
### ChemDose CD87-100 | CD87-200 CD87-200PX | CD87-1000

Chemical Dosimeter Indicator for monitoring disinfection processes by continuous UV-C (254 nm) radiation and pulsed light disinfection systems.

#### **Results Interpretation Guide**











by continuous ov c (254 mm) radiation.

#### **Final Results Example**



### **Main features**

- √ The ink pattern allows the evaluation of the consistency of UV spreading and coverage over the room.
- $\sqrt{\ }$  Thanks to its unique special 3D format, the user can monitor all decontamination parameters in surfaces with different spatial dispositions.
- √ Its distinctive design includes a silicone seal, which allows the pyramid to be placed at different levels, according to the room display and monitoring needs.
- $\sqrt{\mbox{ The indicator}'\mbox{ s base contains a reference chart to mark the position of the indicator.}$



Bionova® BT97 BioSurf Biological Indicator has been designed for guick and easy monitoring of airborne and surface disinfection processes by VHP and HPV. The system consists of two tubes: tube A which contains the spores to challenge the disinfection process, inoculated in a metallic coupon, and tube B which contains the culture medium used to reveal decontamination process success.

### **Advantages**

- √ Super Rapid Biological Indicator for Room Disinfection.
- √ Incubation results in just 1 hour.
- √ Unique in the market.
- √ Easy handling, without cross-contamination.
- √ Evaluation of the actual process, exposing bacteria on a surface directly to H2O2.

- √ Compatible with all Bionova® Fluorescence Automatic Readers.
- ✓ Exclusive holder specially designed for holding in place both tubes in a desired position inside the room to be disinfected.
- √ The Type 1 indicator in the Tube B label allows verifying the correct exposure of this indicator to the decontamination process.



### **BT94**

Specific design for Aerosol H202 disinfection

Readout

- √ Monitoring of airborne and surface disinfection. processes by aerosolized H2O2.
- √ Conventional readout with color change.
- √ Similar configuration as BT97.





### **Advantages**

√ ChemSurf indicators allows monitoring all critical parameters of the disinfection process: time, temperature and H2O2 concentration

Airborne & Surface Disinfection Monitoring Test

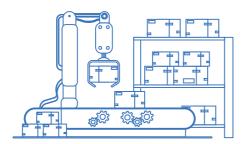
- √ The ink pattern permits to evaluate the homogeneity of H2O2 spreading and coverage over the room.
- √ Special 3D format, unique in the market, which concedes the possibility of monitoring all decontamination parameters in surfaces with different spatial dispositions.
- √ Its distinctive design includes a silicone seal, which allows the pyramid to be placed at different levels, according to the room display and monitoring needs.
- √ The indicator's base contains a reference chart to indicate the position of the indicator and the disinfection equipment location

## CDS47V | CDS47A

ChemSurf indicators have been specially designed to react to Hydrogen peroxide based Airborne and Surface Disinfection. guaranteeing an adequate control of this process efficacy. The ink was developed to change its color when the disinfection process reaches the stated values of the critical variables. Two different products specially designed for each H2O2 disinfection technology.







### **Sterilization Monitoring**

Sterilization procedures should be monitored using biological and chemical indicators. Biological indicators, or spore tests, are the most accepted means of monitoring sterilization because they assess the sterilization processdirectly by killing known highly resistant microorganisms.

Chemical indicators do not guarantee sterilization; however, they help detect procedural errors (e.g., overloaded sterilizer, incorrect packaging) and equipment malfunctions. On the other hand, some chemical indicators should be used inside a package to verify that the sterilizing agent has penetrated it and reached the instruments inside.

## **Biological Indicators**





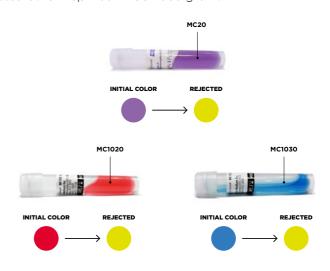
Bionova® Spore Strips consist of an envelope, permeable to the sterilizing agent, containing a paper strip inoculated with a spore population.

After exposure to the sterilization process, strips are aseptically transferred to the culture medium tube and incubated in the Bionova® IC10/20 Dual Incubator according to the specific conditions. If sterilization has failed, culture medium will turn to yellow.

Conversely, if the sterilization process has been successful, the culture medium will remain its original color.

Code	Use	Spore	Compatible Culture Media	Conditions
BT40	EO DRY	Bacillus atrophaeus	MC1020 MC1030	48 hs at 37 °C
BT50	STEAM FORM	Geobacillus stearothermophilus	MC20 MC1020	24 hs at 60 °C 48 hs at 60 °C
BT70	IRRAD	Bacillus pumilus	MC70	48 hs at 37 °C
BT92	VH202	Geobacillus stearothermophilus	MC1020	24 hs at 60 °C
BT93	VH202	Geobacillus stearothermophilus	MC1020	24 hs between 55-62 °C

Bionova® BT93 consists of an envelope containing a stainless steel coupon soaked with a *Geobacillus stearothermophilus* ATCC 7953 spore population. Spore Coupon is specifically designed to control VH2O2 sterilization processes. Spore coupon should be incubated in Bionova® MC1O2O Growth Medium tube or other medium appropriate for *Geobacillus stearothermophilus* ATCC 7953 growth.





# **Self-contained Spore Ampoules**

Bionova® Self-contained Spore Ampoules have been designed for monitoring sterilization of liquids in the pharmaceutical industry. Spore ampoules are made of hermetically sealed type I borosilicate glass, containing a specific population of *Geobacillus stearothermophilus* or *Bacillus subtilis* spores and a specially formulated synthetic culture medium that turns to yellow when spores grow.

Bionova® Self-contained Spore Ampoules provide visual confirmation of sterilization after 48 hours of incubation at 60 °C (BT21, BT22, BT23) or 37 °C (BT24).

### **Advantages**

- $\checkmark$  Easy to use and interpret.
- √ Does not require activation.
- $\checkmark$  Evidence of growth with direct visual confirmation.
- √ For liquid load sterilization monitoring.
- $\checkmark$  Available in packages refrigerated at 4 8 °C, includes negative controls



Code	Conditions	Sterilization
BT21   BT22   BT23	121-134 °C	Steam
BT24	110-121 °C	Steam





### IC10/20

For the incubation of Conventional Self-Contained Bls, Terragene® offers the Bionova® IC10/20 Dual Incubator that provides optimal conditions for the incubation of a wide range of biological indicators (37 °C and 60 °C). It consists of a heating block that also allows to incubate culture media and biological ampoules for sterilization of liquid loads. This incubator has a position for external temperature control (Bionova® TB-IC1020).





With increasing demands for faster sterile instruments turnaround in healthcare facilities, sterilization results need to be available as soon as possible to verify the sterility of the load. To fulfil these needs, Terragene® offers a broad portfolio of fluorescence biological indicators for sterilization monitoring.

- BT224 and BT222 for Steam.
- BT96 for VH202.
- BT102 for Formaldehyde.
- BT110 for Ethylene Oxide.

Ultra Rapid	Super Rapids	Rapids
20	30' 1h	2h 4h C
	7=1	
ANS.	1796 ( 1722 ( 17	Grands  Hill (
STEAM BT224	VH202 STEAM BT96 BT222	FORM EO















Bionova® Auto-readers are automatic systems for incubation and readout of Bionova® Biological Indicators. IC10/20FR and IC10/20FRLCD also allow incubation and readout of Hygiene Monitoring Systems (Chemdye® Pro1 Micro).

The auto-readers allow to work at 2 temperatures (37 or 60 °C) and to select and execute incubation programs in parallel, allowing simultaneous incubation of BIs with

different reading times. They have a thermal printer for the record keeping of results.

The devices can be connected to a PC, which will be able to continuously obtain information about the incubation process and record the results through the Bionova® Cloud Traceability Software.

Bionova® Auto-readers Main Features & Differences	MINIBIO	IC10/20FR	IC10/20FRLCD
DUAL TEMPERATURE SYSTEM (37 °C   60 °C)	~	~	~
SIMULTANEOUS READOUT OF BIONOVA* FLUORESCENSE BIS	~	~	~
NUMBER OF WELLS FOR BI	3	12	12
NUMBER OF WELLS FOR PROTEIN PEN	×	1	1
USB SLOT	~	~	×
ETHERNET CONNECTION	×	×	~
INTERPRETATION OF RESULTS	Color LEDs	Color LEDs	LCD Screen
NUMBER OF SIMULTANEOUS INCUBATION PROGRAMS	3	12	12
VISUAL INFORMATION (IN THE EQUIPMENT) OF THE REMAINING INCUBATION TIME	×	×	~
REMOTE DISPLAY OF THE SCREEN IN PC AND SMARTPHONES	×	×	~
INTERNAL MEMORY STORAGE CAPACITY	Last 3 results	Last 12 results	Last 208 results



# **Biological Indicators**& Incubators Compatibility Chart

		IC10/20	MINIBIO	IC10/20FR	IC10/20FRLCD
	BT10	<b>~</b>			
	BT20	<b>~</b>			
	BT21	<b>~</b>			
\$	BT22	<b>~</b>			
	BT23	<b>~</b>			
4	BT24				
	ВТ30	<b>~</b>			
Ī	BT91	<b>~</b>			
	BT96		<b>~</b>	<b>~</b>	<b>~</b>
	BT100	<b>~</b>			
	BT102		<b>~</b>	<b>~</b>	<b>~</b>
N.	BT110		<b>~</b>	<b>~</b>	<b>~</b>
8	BT222		<b>~</b>	<b>~</b>	<b>~</b>
E	BT224		<b>~</b>	<b>~</b>	<b>~</b>
<u> </u>	Bionova® Culture Mediums	<b>~</b>			

### **Chemical Indicators**





## BD125X/1 | BD125X/2

Chemdye® Bowie-Dick Test Pack was developed to control air removal and steam penetration performance in vacuumassisted steam sterilizers. They are single-use devices that consist of a lead free chemical indicator, BD Test Sheet, placed between porous sheets of paper, wrapped with crepe paper, with a Steam indicator label on the top of the package. Product BD125X/1 also has a Warning Sheet which contains a circular lead free chemical indicator, thus allowing an early detection of air removal failures before they appear on the central chemical indicator



### **Bowie-Dick Test Cards** BD8948X | BD8948X/1 | BD8948H

Chemdye® Bowie-Dick Test Card has been designed to monitor the effectiveness of air removal in vacuum-assisted steam sterilizers at 132 °C. 4 min and at 134 °C. 3.5 minutes. Chemdye® Bowie-Dick Test Card consists of a Type 2 metal free chemical indicator printed on one side of the card. Chemical indicator changes from purple to green when processed. Non-uniform color change indicates presence of an air pocket during the sterilization cycle thus indicating sterilizer malfunction.

BD8948H is a stainless steel re-usable Holder for keeping BD8948X and BD8948X/1 Test Cards in place for proper assessment of sterilization cycle.



## **Double adhesive labels TYPE 1**

Automatic record system labels have been designed to monitor Ethylene Oxide (CD13), Steam (CD23), Dry Heat (CD33), Plasma or Vaporized Hydrogen Peroxide (CD43) and Formaldehyde (CD53) sterilization processes. These self-adhesive labels are used in the outer part of the sterilization packs, stuck to packages or pouches, allowing differentiation between processed and unprocessed items. Their double-adhesive technology allows easy label removal from the sterilization package for data documentation.

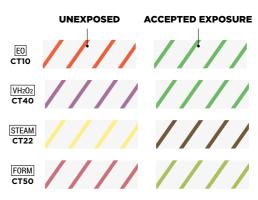
### **Label Gun**

Chemdye® CG3 is a Three-line Automatic Labeler that allows a quick and easy labelling of sterilization packages through the use of special documentation labels. Chemdye® CG3 labeler has three printing lines of twelve alphanumeric digits per line.



## Tapes TYPE 1

Cintape® Self-adhesive tapes have been designed to wrap and seal sterilization packages as well as to distinguish between items that have been exposed to Steam sterilization processes from those that have not. Terragene® has tapes for every sterilization process: Steam (CT22), Ethylene Oxide (CT10), Plasma or Vaporized Hydrogen Peroxide (CT40), Formaldehyde (CT50) and Dry Heat (CT30).



Cintape® CT22 and CT40 are FDA Cleared.

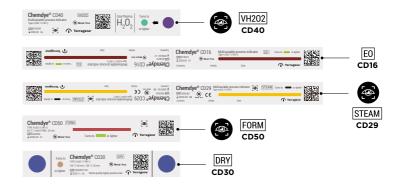




## **Single and double strips TYPE 4**

Chemdye® Type 4 internal control strips are multivariable indicators that rapidly shows if critical parameters of the sterilization process have been reached, ensuring appropriate penetration of the sterilizing agent inside the packages. These chemical indicators offers a distinct color change when exposed to the stated values (SVs) of the critical process variables.







## **Integrator** TYPE 5

It was developed for verification of Steam sterilization cycles between 121 °C and 135 °C. These products ensure an adequate control of the effectiveness of sterilization processes (temperature, time, steam quality).

The accepted final color is reached when a theoretical spore population reaches its kill time, indicating integration condition has been reached.

### **IT12 EO Two level Integrator** TYPE 5



It was developed to control Ethylene Oxide sterilization processes. It is a two-level indicator: Level 1 is the exposure level, which indicates exposure to Ethylene Oxide, while Level 2 is the integration level. This second level consists of a purple/brown ink dot that turns to green as it integrates all critical parameters of the sterilization process (time, temperature, humidity and Ethylene Oxide concentration). This indicator mimics the death curve of a theoretical Bacillus atrophaeus spore population.

### IT26-C **Moving front Integrator** TYPE 5

It was developed for monitoring Steam sterilization processes between 118 °C and 138 °C and to ensure an adequate control of the effectiveness of sterilization processes by monitoring all critical parameters of steam sterilization (temperature, time, steam quality). Chemical pellet melts and migrates as a dark bar along the paper wick. Migration occurs through a zone marked as accept or reject, thus indicating whether sterilization conditions were met or not. The accept result is reached when a theoretical spore population reaches its kill time, indicating integration condition has been reached.







# IT28 | IT27-5YS | IT27-7YS | IT27-18YS TYPE 6

Designed for monitoring Steam sterilization processes. They fulfil the requirements for Type 6 indicators monitoring all the critical parameters of the sterilization process at their position in the chamber, and ensuring an adequate control of the efficacy of the sterilization processes (temperature, time, steam quality).

### **Code** Conditions

IT28 3.5 min. 134 °C | 15 min. 121 °C | IT27-5YS 5 min. 134 °C | 15 min. 121 °C | IT27-7YS 7 min. 134 °C | 20 min. 121 °C | IT27-18YS 18 min. 134 °C

### IT31 TYPE 6

Designed to react to Dry Heat sterilization processes at 160 °C for 40 minutes. Its blue indicating ink has been developed to turn to brown when the process reaches the stated values of the critical process variables for which it has been designed.

Code	Conditions		
IT31	40 min. 160 °C		





## TYPE 4

Chemdve® Chemical tubes have been developed to monitor Steam (CD210, CD220) and Dry Heat sterilization of liquids (CD250) in the pharmaceutical industry. These are easyto-use multivariable indicators, consisting of borosilicate glass tubes of 40 x 7 mm, sealed at both ends. One end is coded by colors to facilitate the identification of the indicator when outside its package. The tube contains 0,25 ml of a thermosensitive red liquid that turns to green when the stated values of the critical process variables of the sterilization process have been reached. The color tubes are calibrated to respond to the specific temperature and time parameters during Steam and Dry Heat sterilization cycles. A permanent color change occurs when the proper parameters have been met at the position of each control tube.

Code	Description	Conditions	Sterilization
CD210	Black spot	15 min. 121 °C 10 min. 126 °C	Steam
CD220	Yellow spot	3-3.5 min. 134 °C	Steam
CD250	White spot	120 min. 160 °C	Dry Heat
		35 min. 180 °C	
		60 min. 170 °C	

### **Performance**

Chemdye® Chemical Tubes can be placed within the product to be sterilized. After exposure to the specific conditions, the reactive ink shows a permanent color change indicating that the parameters of the sterilization have been met.

INITIAL COLOR	REJECTED	FINAL COLOR
	Sense of color change	
	•	

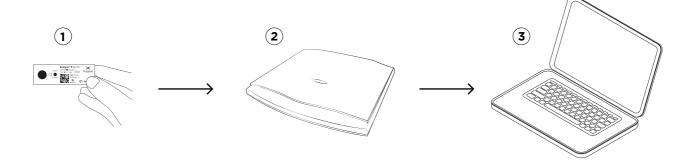


### Trazanto



# Automatic System for Quality & Traceability Control of Washing & Sterilization processes





This innovative and unique system consists of a highly sensitive scanner associated to Bionova® Cloud Traceability Software and in conjunction with Trazanto®, which is our scanner. The scanner along with our traceability software are capable of analyzing and interpreting the results of Chemdye® and Integron® Cleaning and Sterilization Chemical Indicators. In this way, the user is able to collect the results of all the chemical indicators used in all the packs of the same sterilization cycle, or those used in different locations in a cleaning cycle, and to digitally store that information.

Trazanto® System interprets the results in a sensitive and reliable way, thus avoiding possible failures in the operator's visual interpretation. The recording of such results, through the usage of Bionova® Cloud Traceability Software, supports and protects them, by optimizing the results' traceability and availability, generating reports alerts if there are failures in the performance of certain cleaning or sterilization cycles and/or equipment.

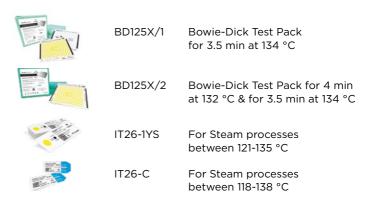
### **Advantages**

- √ Artificial intelligence reading system.
- ✓ Automatic recognition of product code and lot number.
- √ Highly sensitive and easy-to-use scanner.
- √ Associated with Bionova® Cloud Traceability Software that allows the registration and monitoring of results, and the generation and printing of reports.
- $\checkmark$  Prevents possible failures in the operator's visual interpretation.



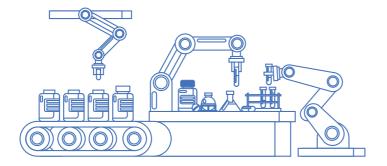
### **Sterilization**

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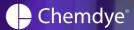






### **Cleaning performance** & Hygiene monitoring

Discover some of the products that we offer to control washing machines performance and for hygiene monitoring with both ATP and protein based systems.



# Indicators for Ultrasonic Cavitation performance test

### **CDWU**

Terragene® offers the Chemdye® CDWU indicator for evaluating the efficiency of the cavitation process from ultrasonic washers.

Chemdye® CDWU indicator consists of a transparent vial, with a bluecolored reactive solution and glass pearls immersed on it. During cavitation, the vibration of the glass pearls triggers a color change in the solution, from blue to yellow, through a range of green color intermediates. When cavitation energy is high enough to guarantee a correct washing of the instruments, the final result will be a yellow coloration, otherwise the indicator will remain greenish, which will show a weak cavitation zone located in that area of the washing machine









# Ultra Rapid Readout

### **Pro1 Alert**

Terragene® has developed the Chemdye® Pro1 Alert Hygiene Monitoring System which not only detects but also quantifies proteins, allergens and reducing agents from different surfaces. The system consists of a pen that has a high absorption swab and two separate reactive solutions contained within the same device. After taking the sample from the selected surface, the swab is returned to the pen, activated and the result is then obtained with 4 minutes of incubation at 60 °C in Bionova® MiniPro Auto-Reader. Chemdye® Pro1 Alert system quantifies with a sensitivity of 0.3 µg of total proteins. The validation of this system reduces the use of multiple and time-consuming specific allergen tests. Its high sensitivity allows to alert the presence of residual proteins from different sources like milk, nuts. gluten, sov. egg, fish and seafood. The system is used along with Bionova® MiniPro auto-reader for analytical analysis.

### **Advantages**

- √ Unique absolute total protein quantification system.
- √ High sensitivity.
- √ Rapid test results in 4 minutes.
- √ Dangerous chemical substances in specialized laboratories.
- √ Quick results that allow taking immediate remedial action.
- √ Manufactured under ISO 15883-1 standard.
- √ Whole traceability using Terragene® Bionova® Cloud Software.
- √ Alternatively provides qualitative data. Comparison of the final color against a color pattern included within the device allows protein/allergen level estimation.







### **MINIPRO**



### **Quantitative analysis**

Bionova® MiniPro is an advantageous and very sensitive tool for incubation and reading of Pro1 Alert hygiene monitoring systems since it offers the user the unique benefit of performing a quantitative analysis of small quantities of protein and allergens, thus providing an exclusive and convenient way to keep results recording and traceability of every surface checked for contaminants. This exclusive feature makes Bionova® MiniPro an innovative device to keep objective track of surface cleaning process monitoring unparalleled on the current market.



### **Time Optimization**

Bionova® MiniPro has 3 incubation positions, thus allowing the incubation of 3 Protein Detection System Pens at the same time.



### **Built-in Thermal Printer**

A thermal printer delivers a ticket showing the final result of each active readout position. This allows to register each result in a record keeping book.



### **Reading & Traceability system**

USB connection for PC record keeping through Bionova® Cloud Reading and Traceability software.



### No maintenance required

The device does not need any kind of routine maintenance



### **Temperature calibration**

The device has an opening on its side to insert a thermometer, which allows temperature calibration control.



### **Compact design**

Bionova® MiniPro is a compact table-top incubator that can be placed anywhere in your facility thanks to its small size



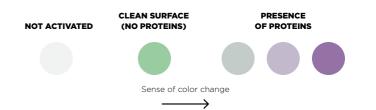
### **Pro1 RT**

Surface cleaning and disinfection are processes applied on regular basis on different working environments like medical centers, bio-pharmaceutical industry, food industry, retail and gastronomy sectors. Residual protein levels on surfaces and rinsing water are an indicator of cleaning efficiency. This is because proteins represent the greatest challenge due to its high surface adhesion, especially when they undergo a denaturation process after being exposed to high temperature. The Chemdye® Pro1 RT Hygiene Monitoring System was designed for the fast and simple protein level determination on instrument's surfaces, hard-to-access areas or in the rinsing water of instruments after cleaning.

The system includes a high absorption swab, which allows the collection of samples from different types of surfaces or solutions with high efficiency. A visual readout of a color change indicates the presence of detectable levels of protein in only 10 minutes allowing to take fast corrective decisions in the presence of contaminants. This system is highly sensitive, detecting from 15 µg of total protein (0.3 mg/ml in solution).

**Rapid** Readout

Incubation Room Temperature 20 to 30 °C







### **Surface ATP Test**

Chemdye® Pen system for ATP quantification used on any surface for hygiene monitoring after the washing or disinfection procedure.

ATP is a molecule present in all living organisms, so it is a good indicator of the presence of microorganisms or residues that may promote their growth. When monitoring begins, the reagent in the test pen vial reacts with the ATP collected on the swab to produce luminescence. The intensity of the light emitted is proportional to the amount of ATP, and, therefore, it is also proportional to the degree of contamination.

### **Characteristics**

- The system has a highly absorbent swab that allows the collection of samples from different surfaces, and a reactive solution.
- The swab is pre-moistened and is capable of releasing the ATP present inside living cells.
- Detection limit: 0.5 femtomol of ATP.
- Quantitative analysis using a specific Luminometer.





### **Bionova® Cloud**

At Terragene® we have developed a complete traceability system for monitoring processes in sterlization and cleaning areas. You can now have access to a complete solution associated with Terragene´s cunsumables. Streamline and automate the traceability associated with chemical indicators (including the Bowie-Dick test), quantitative protein-based hygiene monitoring tests, and for any Bionova® fluorescence readout biological indicator.



## **Get full SPD Quality Control** & Traceability!

### **Advantages**

 $\checkmark$  Get a full and automatic traceability system for all your monitoring processes: hygiene, chemical monitoring and biological monitoring all together.

- √ Avoid human error.
- √ Instant online results.
- $\checkmark$  Speed up all your processes: agile workflow and less time-demanding activities.
- $\checkmark$  Monitor the historical performance of every equipment inside the SPD independently.
- √ Accuracy and efficacy.





### **Bionova® Cloud Compatible Products**

### **Sterilization**



IC1020FR

IC1020FRLCD

MINIBIO

### **Inspection & Hygiene**



TRAZANTO\*

Let's work together to create a better future.



