

000 matachana



## MATACHANA consumables

### Monitoring

Routine monitoring of the validation processes of a RUMED

### Sterile Barrier Systems

Preparation and packaging of the instruments of a RUMED







## Validation **OQPQ**

MATACHANA has a wide range of products designed for specific use in validation processes [Operational Qualification (OQ), Procedure Qualification (PQ)] of RUMED reprocessing devices or laboratories, animal facilities and/or pharmaceutical companies.



## Biosanitary Waste **RBE**

MATACHANA offers the necessary indicators and barriers for managing Special Biosanitary Waste (SBW). From washing indicators, for detecting dirt in washing chambers for containers, to indicators for monitoring SBW sterilization processes. MATACHANA also presents a high range of waste bags for different biorisk groups for SBW centres.



# How should best practices in routine controls and during packaging be carried out?

Consult the flyers for each reprocessing process. For each flyer, there are Work Procedures for including it in your RUMED.

Consult the MATACHANA Newsletter with different updates of the monitoring products and sterile barrier systems.

The image shows several overlapping MATACHANA product flyers and manuals. The top-left flyer is titled 'Indicadores Programa B&D' and includes steps for pre-sterilization, conformity checks, and calculation of indicators. The top-right flyer is 'Indicadores de paquetes (controles internos)' with sections for inspection and selection of indicators. The middle-left flyer is 'MONITORIZACIÓN DE PROCESOS DE ESTERILIZACIÓN POR VAPOR SATURADO' with sections for empty chamber, chamber with load, and efficacy verification. The middle-right flyer is 'Indicadores Biológicos' with sections for selection and collection. The bottom-most flyer is 'Indicadores Biológicos' with sections for selection and collection. The bottom-most flyer also includes a summary of verification and control objectives.



MATACHANA presents high assessment and quality control demands for its consumable products.

MATACHANA's consumable products were evaluated by:

- ISO 17025-certified laboratory with the scope of chemical and biological indicator (ISO 11140-1,4; ISO 11138-1,3,5,7,8, ISO 15883-1,5.) and sterile barrier system standards (ISO 11607-1,2; EN 868-1,2,5,9).
- Matachana Test Centre (MATEC) laboratory that allows product operation to be simulated in real reprocessing conditions.

Therefore, all MATACHANA products contain an infection control seal of guarantee that encompasses a strict and complete quality control represented by the seal:



In addition, the fact that the products are evaluated by the Matachana Test Centre (MATEC) laboratory allows the creation of Interpretation Guides in real conditions with MATACHANA units, not just taking into account the experiment conditions described by the ISO 11138, ISO 11140 and ISO 15883 standards.

The manufacture and design of microbiological and transport barriers are accepted by the Sterile Barrier Association (SBA).

**Make sure that the indicators measure the efficiency of the reprocessing**

1

Strict quality control in production



Differentiating values of MATACHANA consumable products:

Complete range of consumables for all reprocessing processes



3

Technical Engineering Support for resolving customer claims





- Highly-qualified staff for product design and manufacture.
- Automation of production processes.
- Specialist equipment for product evaluation (BIER/CIER according to ISO 18472, ISO 17025-certified laboratory equipment).
- Batch control system using the ISO 2859 AQL (Acceptable Quality Level) Matrix.
- Strict control regarding risk management and preventive actions.
- Storage with controlled temperature and relative humidity.
- Facilities with ISO 7 and ISO 8 particle filtration systems.



- Sterilization indicators.
- Washing indicators.
- Disinfection indicators (all levels of disinfection are taken into account).
- Indicators for endoscope reprocessing, sealer indicators.
- Specific indicators for validation processes.
- Indicators for managing Special Biosanitary Waste (SBW).



Matachana Test Centre is MATACHANA's laboratory that allows reprocessing conditions to be simulated in order to evaluate the operation of the indicators and sterile barrier systems (SBS).



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# Hygiene and disinfection check

## **WASH**

- Pre-washing
- Washing
- Disinfection
- Endoscopy

# WASH

## Pre-washing

### Indicator for ultrasonic baths



#### Indicator for detecting acceptable ultrasonic frequency

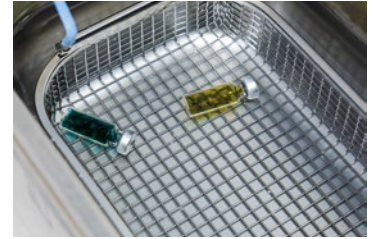
Ref. 85666.2

– 30 vials per box

📅 1 year

🕒 Frequency of use: Once a week

📄 ISO 15883:1,5 AORN, ANSI/AAMI ST98, DH (UK) standards, Joint commission



The spheres at the base of the tube release a colored substance depending on the ultrasonic frequency versus time.

## Washing

### Washing indicators



#### Washing indicator with plastic base (polypropylene)

Ref. 85666.4

– 100 washing strips per box

📅 3 years

🕒 Frequency of use: 1 or 2 per washing rack level

📄 ISO 15883:1,5 AORN, ANSI/AAMI ST98, DH (UK) standards, Joint commission



Stainless steel support with a challenge overlying the indicator.



Steel support with a challenge with grid. Ref. 85667.



#### Washing indicator with stainless steel base

Ref. 94405.6

– Dirt composition (test soil) according to 15883-5

– 100 washing strips per box

📅 2 years

🕒 Frequency of use: 1 or 2 per washing rack level

📄 ISO 15883:1,5 AORN, ANSI/AAMI ST98, DH (UK) standards, Joint commission



Polypropylene plastic support (yellow) with a challenge with grid. Ref. 85604.



Polypropylene plastic support (blue) with an additional challenge to the grid with overlying surface. Ref. 85605.



## Indicator A<sub>0</sub> (thermal disinfection)



### Thermal disinfection indicators

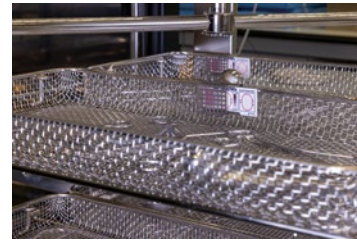
Ref. 85666.3

– 100 washing strips per box

📅 3 years

|||| Frequency of use: 1 per rack

✔ ISO 15883:1,5 AORN, ANSI/AAMI ST98, DH (UK) standards, Joint commission



Indicator A<sub>0</sub> is fitted with the stainless steel support (Ref. 85667) and as a safety note, it must always be fitted on one rack level to obtain the best results.

## Residual protein test



### Swab for sampling medical device surfaces and recesses

Ref. 85668.2

– 2X1 readings for greater reliability

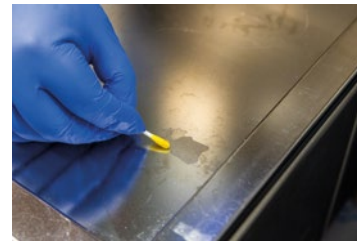
– 50 swabs per box

– The indicator contains the highly specific OPA (o-phthaldehyde) reagent for the peptide bond of proteins

📅 2 years

|||| Frequency of use: 1 per cycle

✔ ISO 15883:1,5 AORN, ANSI/AAMI ST98, DH (UK) standards, Joint commission



Surface sampling in RUMED.



Surface and recess sampling on reusable medical devices.

## Endoscopy

### Process indicators for detecting peracetic acid (PAA)



### Peracetic acid (PAA) indicators

Ref. 85202.2

📅 5 years

|||| Frequency of use: per cycle

✔ ISO 15883-4, DH (UK) standards





# WASH

## Biological indicators for high-level disinfection



Biological indicator with a population of  $10^9$  *Enterococcus faecium* ATCC 6057

Ref. 94405.5

📅 3 months

📅 Frequency of use: per week

📄 ISO 15883-4, DH (UK) standards



## Biological indicators for sterilization at the point of use



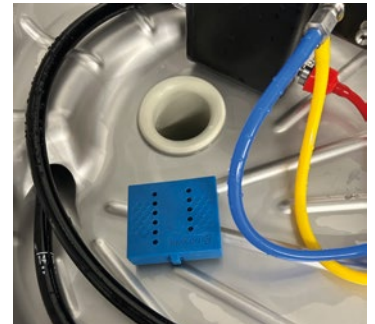
Biological indicator with a population of  $10^6$  *Bacillus atrophaeus* ATCC 9372

Ref. 85027.1 and 85028.1

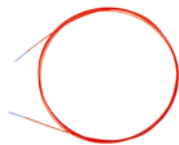
📅 2 years

📅 Frequency of use: per week

📄 ISO 15883-4, DH (UK) standards



## Flexible endoscopy brushes for endoscope sampling using residual protein testing



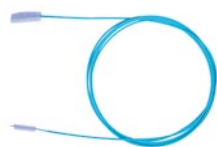
2.3 m double-ended endoscopy brush

Ref. 96337.5

– Working channel gauge: 1.2-1.8 mm



Air/water channel sampling using the endoscopy brush.



2.3 m double-ended endoscopy brush

Ref. 96337.1

– Working channel gauge: 2.8-4.5 mm



Endoscopy brush bristle sampling using residual protein testing.



# Preparation and packaging

**SEAL**

**SBS**

- Heat sealing
- Sterile barrier systems



# SEAL

## Heat sealing

### Indicators for sheet-type heat sealers



#### Indicators for paper/film-type heat sealers

Ref. 85692.9

– 250 sheets per box

📅 3 years

📏 Frequency of use: 1 sheet/day

✅ ISO 11607-2. ASTM F1929-98:2004, EN 868-5, AORN, DH (UK) standards, Joint commission



Results after sealing the paper/film sealing sheets. See even stitching as a favourable outcome.



#### Indicators for sheet-type heat sealers for Tyvek® film

Ref. 85692.7

– 250 sheets per box

📅 3 years

📏 Frequency of use: 1 sheet/day

✅ ISO 11607-2. ASTM F1929-98:2004, EN 868-9, AORN, DH (UK) standards, Joint commission



Results after sealing the Tyvek® film sealed sheets. See even stitching as a favourable outcome.

### Indicators for ink-type heat sealers

#### Indicators for paper/film ink-type heat sealers

Ref. 85692.6

– 1 x 100 ml ampoule + Pasteur pipette

📅 3 years

📏 Frequency of use: 1 sheet/week

✅ ISO 11607-2. ASTM F1929-98:2004, EN 868-5, AORN, DH (UK) standards, Joint commission



Results after sealing by applying ink for paper/film. Check there are no ink leaks as a favourable outcome.

#### Indicators for ink-type heat sealers for Tyvek® film

Ref. 85692.8

– 1 x 100 ml ampoule + Pasteur pipette

📅 3 years

📏 Frequency of use: 1 sheet/week

✅ ISO 11607-2. ASTM F1929-98:2004, EN 868-9, AORN, DH (UK) standards, Joint commission



Results after sealing by applying ink for Tyvek® film. Check there are no ink leaks as a favourable outcome.



## Sterile barrier systems

### Paper/film (mixed)



#### Paper/film reels/rolls

- Compatibility with Steam, LTSF and Ethylene Oxide sterilization processes

3 years

Standards ISO 11607-1, EN 868-5

MIXED REEL		
85840.1	50 mm x 200 m	6 units/box
85841.1	75 mm x 200 m	4 units/box
85842.1	100 mm x 200 m	4 units/box
85843.1	150 mm x 200 m	4 units/box
85844.1	200 mm x 200 m	2 units/box
85845.1	250 mm x 200 m	2 units/box
85846.1	300 mm x 200 m	2 units/box
85847.1	400 mm x 200 m	1 unit/box
85848.1	500 mm x 100 m	1 unit/box



#### Self-sealing paper/film bags

- Compatibility with Steam, LTSF and Ethylene Oxide sterilization processes

3 years

Standards ISO 11607-1, EN 868-5

SELF-SEALING MIXED BAG		
85800.2	90 x 200 mm	200 units/box
85801.2	90 x 230 mm	200 units/box
85802.2	140 x 280 mm	200 units/box
85802.3	130 x 250 mm	200 units/box
85804.2	130 x 330 mm	200 units/box
85805.2	200 x 330 mm	200 units/box
85806.2	300 x 390 mm	400 units/box
85807.2	300 x 450 mm	400 units/box

**Paper/film bags without self-sealing**

– Compatibility with Steam, LTSF and Ethylene Oxide sterilization processes



 3 years

 Standards ISO 11607-1, EN 868-5



MIXED BAG WITHOUT SELF-SEALING		
85535	75 x 150 mm	2700 units/box
85535.1	75 x 210 mm	2500 units/box
85535.2	100 x 240 mm	2400 units/box
85535.3	100 x 280 mm	2400 units/box
85535.4	100 x 580 mm	2000 units/box
85535.5	150 x 280 mm	2000 units/box
85535.6	150 x 360 mm	2000 units/box
85535.7	200 x 360 mm	1800 units/box
85535.8	200 x 320 mm	1800 units/box
85535.9	250 x 360 mm	600 units/box
85536	300 x 420 mm	600 units/box
85536.1	300 x 500 mm	600 units/box
85536.2	400 x 580 mm	600 units/box
85536.3	300 x 580 mm	600 units/box

**Tyvek® film**

**Tyvek® film  
reels/rolls**

– Compatibility with Vaporised Hydrogen Peroxide sterilization processes



 3 years

 Standards ISO 11607-1, EN 868-9

TYVEK® REEL		
85661.0	75 mm x 70 m	4 units/box
85661.1	100 mm x 70 m	4 units/box
85661.3	150 mm x 70 m	4 units/box
85661.5	200 mm x 70 m	2 units/box
85661.7	250 mm x 70 m	2 units/box
85661.9	300 mm x 70 m	2 units/box
85662	400 mm x 70 m	1 unit/box
85662.1	500 mm x 70 m	1 unit/box



### Tyvek® film bags

– Compatibility with Vaporised Hydrogen Peroxide sterilization processes

📅 3 years

✅ ISO 11607-1, EN 868-9 standards

TYVEK® BAG		
85663	75 x 70 mm	1000 units/box
85663.1	100 x 70 mm	1000 units/box
85663.2	150 x 70 mm	1000 units/box
85663.3	200 x 70 mm	350 units/box
85663.4	250 x 70 mm	350 units/box
85663.5	320 x 70 mm	400 units/box
85663.6	400 x 70 mm	350 units/box

### Transport and protection sheets



**With a single layer of propylene – Spunbond.**  
Optimal contrast color for detecting rips and tears

– Compatibility with Steam, LTSF, Ethylene Oxide and Vaporised Hydrogen Peroxide sterilization processes

📅 3 years

✅ ISO 11607-1, EN 868-2,3,6 standards

VIOLET TRANSPORT COVER SHEETS		
85122	75 mm x 75 mm (160 units/box)	160
85122.0	90 mm x 90 mm (120 units/box)	120
85122.1	100 mm x 100 mm (120 units/box)	120
85122.2	120 mm x 120 mm (96 units/box)	96

### Microbiological and protection and/or transport barrier sheets



**With a triple layer of Spunbond-Meltblown-Spunbond propylene, blue in color and 40 g/m<sup>2</sup>**

– Compatibility with Steam, LTSF, Ethylene Oxide and Vaporised Hydrogen Peroxide sterilization processes

📅 3 years

✅ ISO 11607-1, EN 868-2,3,6 standards

BLUE SMS 40 G/M <sup>2</sup>		
85531.6	50 mm X 50 mm (250 units/box)	250
85531.7	60 mm x 60 mm (220 units/box)	220
85531.8	75 mm X 75 mm (90 units/box)	90
85531.9	90 mm x 90 mm (80 units/box)	80
85532	100 mm x 100 mm (70 units/box)	70
85532.1	120 mm X 120 mm (50 units/box)	50



## Interleaved or interlaminated sheets



**With a triple layer of Spunbond-Meltblown-Spunbond polypropylene**  
**Green microbiological sheet-40 g/m<sup>2</sup>**  
**Blue transport and/or protection sheet-55 g/m<sup>2</sup>**

– Compatibility with Steam, LTSF, Ethylene Oxide and Vaporised Hydrogen Peroxide sterilization processes

 3 years

 ISO 11607-1, EN 868-2,3,6 standards



INTERLEAVED SMS 55 g/m <sup>2</sup> GREEN - BLUE		
85212	40 g/m <sup>2</sup> , 90 cm x 90 cm (60 units/box)	60
85212.1	40 g/m <sup>2</sup> , 100 mm x 100 mm (60 units/box)	60
85212.2	40 g/m <sup>2</sup> , 120 mm x 120 mm (50 units/box)	50
85212.3	40 g/m <sup>2</sup> , 137 mm x 137 mm (40 units/box)	40

## Crepe paper sheets - Microbiological sheet



**With a layer of green cellulose – microbiological sheet.**  
**Optimal contrast color for detecting rips and tears**

– Compatibility with Steam, LTSF sterilization processes

 3 years

 Standards ISO 11607-1, EN 868-2.3

CREPE PAPER SHEETS		
85534	60 mm x 60 mm (400 units/box)	400
85534.1	75 mm x 75 mm (175 units/box)	175
85534.2	90 mm x 90 mm (125 units/box)	125
85534.3	100 mm x 100 mm (125 units/box)	125
85534.4	120 mm x 120 mm (100 units/box)	100

## Absorbent cellulose sheets



**Use in cases of possible risks of excess condensation and wet loads for Saturated Steam sterilization processes**

– Compatibility with Steam sterilization processes

 3 years

 ISO 11607-1 standards

ABSORBENT CELLULOSE SHEETS		
85537.3	300 mm x 300 mm (1000 units/box)	1000
85537.0	300 mm x 600 mm (500 units/box)	500
85537.1	250 mm X 500 mm (1000 units/box)	1000
85537.2	150 mm X 250 mm (3000 units/box)	3000



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COG metachana



HPO



metachana

BIOVelox20e

BIOVelox20<sup>®</sup>  
INCUBATOR



Loading



# Sterilization

**STEAM**

**FORM**

**VH2O2**

- Saturated Steam sterilization
- Low Temperature Steam and Formaldehyde (LTSF) sterilization
- Vaporised Hydrogen Peroxide (vH<sub>2</sub>O<sub>2</sub>) sterilization



## STEAM

### Saturated Steam sterilization

Type 2 indicators (Indicators that use a process challenge device, PCD)





#### B&D package

Ref. 85010

- Indicator value (SV):  
134 °C 3 minutes 30 seconds  
and 121 °C 15 minutes
- Use in health centres  
and laboratories
- 20 x B&D packages per box

 4 years

 Frequency of use: 1 package  
per day per sterilizer in  
the B&D program

 ISO 11140-1,4, AORN,  
ANSI/AAMI ST79, DH (UK)  
standards, Joint commission

#### PCD-Helix for bench top sterilizer/table top sterilizer


Ref. 85686


#### PCD-Helix for sterilizers


Ref. 85686.1

- Indicator value (SV): 134 °C  
3 minutes 30 seconds and  
121 °C 15 minutes
- Use in health centres  
and laboratories
- 250 chemical strips + 1 PCD

 4 years

 Frequency of use: 1 PCD per  
day per bench top sterilizer/  
table top sterilizer

 Frequency of use: 1 PCD per day  
per sterilizer in the B&D program  
or also in programs with load

 ISO 11140-1,6, AORN,  
ANSI/AAMI ST79, DH (UK)  
standards, Joint commission



Use of the B&D and PCD-Helix  
package in the B&D program.  
Always place 10-20 cm from  
the base of the steriliser and near  
the sterilization chamber drain  
according to ISO 17665-1.2.

**Process or external indicators**





**Steam tapes**

Dimensions 19 cm x 50 m  
**Ref. 85888**

Dimensions 25 cm x 50 m  
**Ref. 85888.1**

- Use in health centres and laboratories
- 10 tapes per box



-  4 years
-  ISO 11140-1 standards

**Documentation and logging systems.**

**Steam labels with type-1 indicator**

**Ref. 85031**

- Use in health centres and laboratories
- 9000 labels per box

-  4 years
-  ISO 11140-1 standards



MATACHANA label gun with 3 alphanumerical lines.





**Documentation and logging systems.**

**Steam labels with type-1 indicator**

**Ref. 78761.1**

- Use in health centres
- 1100 labels per box

-  4 years
-  ISO 11140-1 standards



Zebra ZD421t model printers.





## Package indicators


### Multivariable chemical indicator or type 4


Ref. 85012

- Indicator value (SV):  
134 °C 3 minutes 30 seconds  
121 °C 15 minutes
- Use in health centres
- 500 indicators per box



 4 years

 Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

 ISO 11140-1 standards


### Integrating chemical indicator or type 5

Ref. 85013.2, 85013.4

- Indicator value (SV): 134 °C 3 minutes 30 seconds  
121 °C 16.5 minutes
- Use in health centres and laboratories
- 400 indicators per box (Ref. 85013.2)
- 3200 indicators per box (Ref. 85013.4)



 4 years

 Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

 ISO 11140-1, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission


### Emulating chemical indicator or type 6


Ref. 85015.2

- Indicator value (SV):  
134 °C 3 minutes 30 seconds  
121 °C 15 minutes
- Use in health centres and laboratories
- 400 indicators per box



 4 years

 Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

 ISO 11140-1, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission





### Emulating chemical indicator or type 6 for prion programs

Ref. 85018.1

- Indicator value (SV): 134 °C 18 minutes
- Use in health centres
- 400 indicators per box

 4 years

 Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

 ISO 11140-1, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission



Location of the package indicator in a container. It is recommended to place the indicators in close contact with the RMDs. It is recommended to fold the strip in cases where there is a risk of contact of the indicator ink with the plastic and metal surfaces of the barriers (bags or containers) or the DMR itself.

## Self-contained biological indicators (colorimetric)





### Self-contained biological indicator (SCBI) for Steam

Ref. 85022

- Incubation time 24 hours
- *Geobacillus stearothermophilus* ATCC 7953 spores  
FBIO<sub>121 °C</sub> ≥ 9 min
- Use in health centres and laboratories
- 50 indicators per box

 2 years

 Frequency of use: 1 per cycle

 ISO 11138-1,3, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission


### Self-contained biological indicator (SCBI) for Steam Instant Release

Ref. 85024

- Immediate chemical reaction time = Incubation time 24 hours
- *Geobacillus stearothermophilus* ATCC 7953 spores  
FBIO<sub>121 °C</sub> ≥ 9 min
- Use in health centres. Especially for primary care centres or dental clinics
- 50 indicators per box

 2 years

 Frequency of use: 1 per cycle

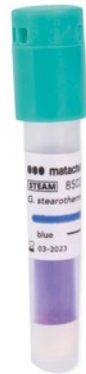
 ISO 11138-1,3, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission



Incubator for self-contained biological indicators (colorimetric) (Ref. 85208). Programmable to 55-60 °C for *Geobacillus stearothermophilus* ATCC 7953. Programmable to 33-37 °C for *Bacillus atropheus* ATCC 9372.



Self-contained biological indicators (enzymatic) (fast)



**BIOVelox20® self-contained biological indicators (SCBI) for Steam**

Ref. 85022.1

- Fast incubation time  
20 min. *Geobacillus stearotherophilus* spores  
ATCC 7953 FBIO<sub>121 °C</sub> ≥ 9 min  
Use in health centres
- 50 indicators per box



2 years



Frequency of use: 1 per cycle



ISO 11138-1,3, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission



BIOVelox20® incubator (Ref. 85208.0)

Fluorescence readings for the detection of the enzymatic activity of  $\alpha$  and  $\beta$  glucosidases in the *Geobacillus stearotherophilus* ATCC 7953 and *Bacillus atrophaeus* ATCC 9372 spores, respectively.

Programmable to 55-60 °C for *Geobacillus stearotherophilus* ATCC 9753.

Programmable to 33-37 °C for *Bacillus subtilis* ATCC 9372.

**Characteristics  
INCUBATOR  
BIOVelox20®**



**+ Speed**

Fast incubations of up to 20 minutes for the main sterilization processes: Saturated Steam, Low Temperature Steam and Formaldehyde (LTSF) and Hydrogen Peroxide Steam (vH2O2).

**+ Traceability**

Recording of automatic results with the option of digitalising them in the centralised traceability software of the sterilization centres.

**+ Safety**

Availability of functional, temperature calibration and fluorescence verification reports for the BIOVelox20® incubator with an exclusive technical panel for carrying out the necessary requalifications annually. This adjustment is essential to obtain the safety provided by the BIOVelox20® biological indicators with rapid fluorescence reading.

**+ Complementarity**

The BIOVelox20® incubator is complementary, with 4 sterilization processes and for user purposes, it allows the simultaneous incubation of the 3 main sterilization processes (Saturated Steam, LTSF and vH2O2).



## Low Temperature Steam and Formaldehyde (LTSF) sterilization

### Type 2 indicators

(Indicators that use a process challenge device, PCD)




#### PCD-Helix for LTSF

Ref. 85431.5

- Indicator value (SV):  
60 °C 30 minutes FA at 3% (v/v)
- 78 °C 10 minutes FA at 3% (v/v)
- Use in health centres
- 250 chemical strips + 1 PCD

 4 years

 Frequency of use: 1 indicator per cycle

 ISO 11140-1.6 standards

### Package indicators


#### Multivariable chemical indicator or type 4


Ref. 85274

- Indicator value (SV):  
60 °C 30 minutes FA at 3% (v/v)
- 78 °C 10 minutes FA at 3% (v/v)
- Use in health centres
- 500 indicators per box



 4 years

 Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

 ISO 11140-1 standards

### Process or external indicators type 1


#### LTSF tape


Ref. 85693.2

- Dimensions 19 mm x 50 m
- Use in health centres



 4 years

 Frequency of use: 1 indicator per cycle

 ISO 11140-1 standards

# FORM


## Documentation and logging system


### LTSF label

Ref. 85277

– Use in health centres

 4 years

 Frequency of use: 1 indicator per cycle

 ISO 11140-1 standards




### LTSF labels with type-1 indicator

Ref. 78761.4

– Use in health centres  
– 1000 labels per box

 4 years

 ISO 11140-1 standards



Zebra ZD421t model printers.

## Biological indicators

### Self-contained biological indicator (SCBI) for LTSF

Ref. 85270


– Incubation time 48 hours.

*Geobacillus stearothermophilus* ATCC 7953 spores  $\text{FBIO}_{\text{FA } 60^\circ\text{C}} \geq 30 \text{ min}$

– Use in health centres.  
– 50 indicators per box

 2 years

 Frequency of use: 1 per cycle

 ISO 11138-1.5 standards

Compatible with incubator for self-contained biological indicators (colorimetric) Ref. 85208



### BIOVelox20® fast self-contained biological indicators (SCBI) for LTSF

Ref. 85270.1

– Fast incubation time 20 min

*Geobacillus stearothermophilus* ATCC 7953


spores  $\text{FBIO}_{\text{FA } 60^\circ\text{C}} \geq 30 \text{ min}$

Use in health centres.

– 50 indicators per box

 2 years

 Frequency of use: 1 per cycle

 ISO 11138-1.5 standards

Compatible with BIOVelox20® incubator (enzymatic) Ref. 85208.0



## Vaporised Hydrogen Peroxide (vH2O2) sterilization

Type 2 indicators (Indicators that use a process challenge device, PCD)



### PCD-Helix for vH2O2

Ref. 85202

- Indicator value (SV): 50 °C 6 minutes 2.3 mg/l H<sub>2</sub>O<sub>2</sub>
- Use in health centres
- 250 chemical strips + 1 PCD

📅 4 years

|||| Frequency of use: 1 indicator per cycle

✔ ISO 11140-1.6 standards

## Package indicators



### Multivariable chemical indicator or type 4

Ref. 85203

- Indicator value (SV): 50 °C 6 minutes 2.3 mg/l H<sub>2</sub>O<sub>2</sub>
- Use in health centres
- 500 indicators per box

📅 4 years

|||| Frequency of use: 1 per sterilization container (package, bag and container) in each cycle

✔ ISO 11140-1 standards

## Process or external indicators



### vH2O2 tape

Ref. 85693.3

- Dimensions 19 mm x 60 m
- Use in health centres

📅 4 years

|||| Frequency of use: 1 indicator per cycle

✔ ISO 11140-1 standards



### vH2O2 label

Ref. 85210

- Use in health centres

📅 4 years


|||| Frequency of use: 1 indicator per cycle

✔ ISO 11140-1 standards



**Biological indicators (colorimetric and fast)****Self-contained biological indicator (SCBI) for vH2O2****Ref. 85207**

- Incubation time 48 hours  
*Geobacillus stearothermophilus* ATCC 7953  
spores  $\text{FBIO}_{\text{vH2O2 } 50^\circ\text{C}} \geq 10 \text{ min}$   
Use in health centres.
- 50 indicators per box

 2 years Frequency of use: 1 per cycle ISO 11138-1 standards, Deinhard et al. 2015

Compatible with incubator for self-contained biological indicators (colorimetric) Ref. 85208

**BIOVelox20® fast self-contained biological indicators (SCBI) for vH2O2****Ref. 85207.1**

- Fast incubation time 20 min
- *Geobacillus stearothermophilus* ATCC 7953  
spores  $\text{FBIO}_{\text{vH2O2 } 50^\circ\text{C}} \geq 10 \text{ min}$
- Use in health centres
- 50 indicators per box

 2 years Frequency of use: 1 per cycle ISO 11138-1 standards, Deinhard et al. 2015

Compatible with BIOVelox20® incubator (enzymatic) Ref. 85208.0

# Validation indicators

(Operational Qualification,  
Procedure Qualification)

**OQPQ**

110 Spore Disc on  
glass fiber carrier  
VH202  
Lot 4103 2123 08-2023  
BL4103 V01

- Washing and disinfection indicators
- Sterilization indicators

## Washing and disinfection indicators



### Heparinised sheep blood with protamine sulphate (10 ml)

Ref. 85666.7

- Dirt test according to ISO 15883-1,2,5



### BCA protein detection kit

Ref. 85666.8

- Indicator for the detection of organic matter with bicinchoninic acid according to ISO 15883-1.2. Quantitative method



### Indicators for OPA residual protein testing

Ref. 85668.2

- Indicator for the detection of organic matter with ortho-phthaldehyde solution according to ISO 15883-1.2. Semi-quantitative method



### Indicators for checking high-level disinfection

Ref. 94405.5

- Indicators for checking disinfection on critical medical devices
- *Enterococcus faecium* ATCC 6057 10<sup>9</sup> UFC/strip



### Indicators for checking low-level disinfection

Ref. 85666.5

- Indicators for checking disinfection on non-invasive medical devices
- *Enterococcus faecium* ATCC 6057 10<sup>5</sup> UFC/strip





### PCDs for disinfection indicators on critical devices

Ref. 85667.5, 94405.8, 94405.9

- Receptacle for the introduction of high-level disinfection indicators
- PCD for MIC (minimally invasive surgery)

## Sterilization indicators



### Spore strips for sterilization processes

- Spore strips for Steam and LTSF  
Ref. 85027 for vH<sub>2</sub>O<sub>2</sub> Ref. 85029
- Different substrates: metal and filter paper
- *Geobacillus stearothermophilus* ATCC 7953 spores FBIO<sub>121 °C</sub> ≥ 9 min
- *Geobacillus stearothermophilus* ATCC 7953 spores FBIO<sub>FA 60 °C</sub> ≥ 30 min
- *Geobacillus stearothermophilus* ATCC 9753 spores FBIO<sub>vH<sub>2</sub>O<sub>2</sub> 50 °C</sub> ≥ 10 min
- Incubation time 48 hours



### Spore discs for sterilization processes

- Spore discs for vH<sub>2</sub>O<sub>2</sub> Ref. 85608
- *Geobacillus stearothermophilus* ATCC 9753 spores  
FBIO<sub>vH<sub>2</sub>O<sub>2</sub> 50 °C</sub> ≥ 10 min
- Incubation time 48 hours



### Spore strips for sterilization processes at the point of use

- Spore strips for PAA, Ref. 85027.1
- *Bacillus atrophaeus* ATCC 9372



### Culture media

Culture media for spore discs and strips  
for Steam and vH2O2

**Ref. 85028**

- Spore strips for LTSF  
Ref. 85030 (purple)
- Culture media for spore strips for PAA  
Ref. 85028.1 (green)



### Ampoules for liquid media sterilization processes

**Ref. 85025**

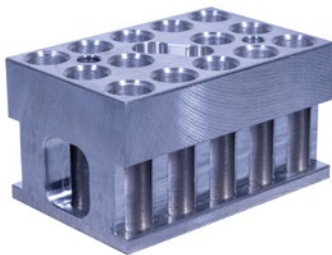
- Ampoules 1.5 ml  $10^6$  *Geobacillus stearothermophilus*
- Incubation time 24 hours
- *Geobacillus stearothermophilus* ATCC 7953 spores  
FBIO<sub>121 °C</sub> ≥ 9 min



### Ampoules for liquid media sterilization processes

**Ref. 85025.1**

- Ampoules 0.2 ml  $10^6$  *Geobacillus stearothermophilus*
- Incubation time 24 hours
- *Geobacillus stearothermophilus* ATCC 7953 spores  
FBIO<sub>121 °C</sub> ≥ 9 min



### Aluminium block for biological indicator incubator for incubating ampoules and culture media

**Ref. 85208.1**

- Ref. 85208.1 Ampoules
- Ref. 85208.2 Culture media



# Indicators and barriers for Special Biosanitary Waste (SBW) management centres

**RBE**

- Washing indicators
- Sterilization indicators
- Special Biosanitary Waste (SBW) bags




## Washing indicators





### Residual protein test

Ref. 85668.2

- Swab for sampling medical device surfaces and recesses
- 2 readings in 1 + reliability
- 50 swabs per box

 2 years

 Frequency of use: 1 per cycle

 ISO 15883:1,5 AORN, ANSI/AAMI ST79 (7.5.3.3), DH (UK) standards, Joint commission

The indicator contains the highly specific OPA (o-phthalaldehyde) reagent for the peptide bond of proteins

## Sterilization indicators





### B&D package

Ref. 85010

- Indicator value (SV):  
134 °C 3 minutes 30 seconds
- 121 °C 15 minutes
- Use in health centres and laboratories
- 20 x B&D packages per box

 4 years

 Frequency of use: 1 package per day per steriliser in the B&D program

 ISO 11140-1,4, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission


### Self-contained biological indicator (SCBI) for Steam


Ref. 85022

- Incubation time 24 hours
- *Geobacillus stearothermophilus* ATCC 7953 spores  
FBIO<sub>121 °C</sub> ≥ 9 min
- Use in health centres
- 50 indicators per box



 2 years

 Frequency of use: 1 per cycle

 ISO 11138-1,3, AORN, ANSI/AAMI ST79, DH (UK) standards, Joint commission

## Special Biosanitary Waste (SBW) bags



### Hot melt (polyethylene) and non-hot melt (polypropylene) SBW bags

Ref. 85425

- Bag with grammages of between 120 and 500 gauges
- Different colored bags (red, yellow, green and black)
- Bags for different biorisk groups

# Guide to indicator results





## 1. Pre-washing indicators

Pre-washing indicators	Not processed	Acceptable result
Ultrasonic bath indicator Ref. 85666.2		




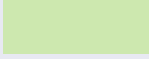








## 2. Washing indicators

Washing indicators	Not processed	Acceptable result
High performance washing indicator Ref. 85666.4		
Indicator A0 Ref. 85666.3		
Washing indicator Ref. 94405.6		
Residual protein testing Ref. 85668.2		









## 3. Indicators for endoscope reprocessing

Indicators for endoscope reprocessing	Not processed	Acceptable result
Process indicator Ref. 85202.2		
Washing indicator Ref. 94405.6		

## 4. Microbiological and protection barriers

Microbiological and protection barriers	Not processed	Acceptable result
Mixed/Tyvek® bags Ref. 85800.2 Ref. 85663	STEAM <b>STEAM</b>	
		
	FORMALDEHYDE <b>FORM</b>	
		
	ETHYLENE OXIDE <b>VH2O2</b>	
		
Mixed/Tyvek® reels Ref. 85840.1, 85610	STEAM <b>STEAM</b>	
		
	FORMALDEHYDE <b>FORM</b>	
		
	ETHYLENE OXIDE <b>VH2O2</b>	
		

## 5. Sterilization indicators. Process challenge device

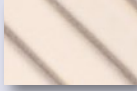
Process challenge device	Not processed	Acceptable result
Bowie & Dick for operating rooms Ref. 85010		
PCD – Helix Ref. 85686, 85686.1, 85687		
PCD – Helix for Plasma (H <sub>2</sub> O <sub>2</sub> ) Ref. 85202		
PCD – Helix for Formaldehyde Ref. 85431.5		










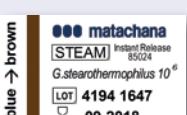









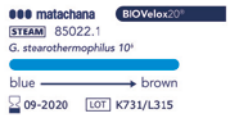

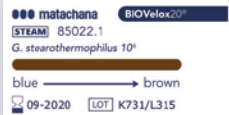

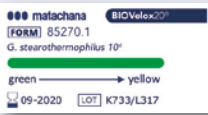



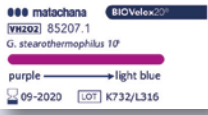

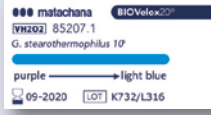
## 6. Sterilization indicators. Indicators for packages and containers

Indicators for containers	Not processed	Acceptable result
<p>Multivariable chemical indicator type 4 Ref. 85012</p>		
<p>Integrating chemical indicator type 5 Ref. 85013.2</p>		
<p>Emulating chemical indicator type 6 Ref. 85015.2</p>		
<p>Multivariable chemical indicator for Peroxide type 4 Ref. 85203</p>		
<p>Multivariable chemical indicator for Formaldehyde type 4 Ref. 85274</p>		
<p>Emulating chemical indicator for prions type 6 Ref. 85018.1</p>		

## 7. Sterilization indicators. Process indicators

Packaging	Not processed	Acceptable result
Adhesive tape for Steam packaging Ref. 85888, 85888.1		
Adhesive tape for Formaldehyde packaging Ref. 85693.2		
Adhesive tape for Plasma packaging Ref. 85693.3		
Labels for registering Steam containers Ref. 85031		
Labels for registering Plasma containers Ref. 85210		
Labels for registering Formaldehyde containers Ref. 85277		

## 8. Sterilization indicators. Biological indicators

Biological indicators	Not processed	Acceptable result
Self-contained biological indicator (SCBI) for Steam Ref. 85022	 	 
Self-contained biological indicator (SCBI) for Steam Instant Release Ref. 85024	 	 
Self-contained biological indicator (SCBI) for Plasma Ref. 85207	 	 
Self-contained biological indicator (SCBI) for Formalin Ref. 85270	 	 
BIOVelox20® biological indicator for Steam Ref. 85022.1	 	 
BIOVelox20® biological indicator for LTSF Ref. 85270.1	 	 
BIOVelox20® biological indicator for vH2O2 Ref. 85207.1	 	 





## Innovation is the way forward

MATACHANA, a family-owned company founded in 1962, is a world leader in the manufacture of steam sterilization equipment, diverse low temperature sterilization technologies, as well as washing and thermal disinfection equipment, providing comprehensive solutions for the Healthcare, Life Science and Pharma sectors.

Since the company's foundation more than 60 years ago, our mission has been to provide the best service, bringing our knowledge and field experience to our customers to facilitate their daily work, allowing them to be efficient in production while rigorously maintaining quality.

MATACHANA has a worldwide presence, with offices based in Spain, France, Germany, Italy, Portugal and Indonesia, or through its distributors in over 120 countries.

We are aware that training and service contribute decisively to achieve customer satisfaction. For this reason, we have always invested in the improvement of these two areas of activity, which allows us to maintain direct contact with our customers and to jointly develop a continuous improvement process.

### Technical engineering support

Assistance is provided by engineers, highly expert technicians, and support staff committed to guarantee proper equipment operation and condition.

### MIEC, training centre

We are firmly committed to and demand optimum operation from the MATACHANA equipment, and for this reason we invest in the training of future users. We offer training courses to all our customers on a regular basis, on all 5 continents.

### Environmentally friendly

The company has four production sites in Europe. The equipment is designed and manufactured using the latest technologies on the market to ensure minimal water and energy consumption. Our production centre located in Castelldefels (Barcelona, Spain) complies with the ISO 14001 standard on environmental management.

### Quality

MATACHANA equipment is designed, manufactured and tested within a quality control system according to the international ISO 9001 and EN ISO 13485 standards for the quality management of medical devices.



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#### Offices in Spain, France, Germany, Italy, Portugal and Indonesia

Present in over 120 countries