

# COVID-19

Nadie mejor para protegerte que Pharmediq



FARMACÉUTICA  
DEL PRINCIPADO  
DE ASTURIAS



# PRODUCTOS

## MASCARILLAS

Quirúrgica Adulto  
Quirúrgica Infantil  
FFP2 Adulto  
FFP2 Infantil  
FFP3

## ROPA DE PROTECCIÓN

### Batas

Bata 25gr  
Bata 35gr  
Bata 40gr  
Bata 60gr  
Bata Laminada 55gr  
Bata Laminada 70gr  
Bata Reforzada  
Bata Baymed EN14126 56gr  
Bata Reutilizable  
Bata Sin Mangas  
Bata Polietileno  
Delantal Polietileno  
Bata Visita 20gr  
Bata Visita 30gr  
Pijama Paciente 2 piezas 40gr

### Buzos

Buzo Cat I  
Buzo Cat III Tipo 5/6  
Buzo Cat III Tipo 3B/4B

## COMPLEMENTOS

Gorro Quirúrgico  
Gorro Polipropileno  
Capucha  
Calzas Polietileno  
Calzas Polipropileno  
Cubre-botas Polietileno  
Cubre-botas Polipropileno  
Manguitos Polietileno  
Manguitos Polipropileno puño elástico  
Manguitos Polipropileno puño de punto

## PANTALLA Y GAFAS PROTECTORAS

Gafa Integral  
Gafa Visita  
Pantalla Protección

## GELES Y DESINFECCIÓN

Gel hidroalcohólico 500ml  
Gel hidroalcohólico 5L  
Pulsera dosificadora de gel  
Dispensador básico  
Dispensador automático  
Desinfectante de superficies 750ml  
Desinfectante de superficies 5L

## DISPOSITIVOS

Termómetros infrarrojos  
Estación de termometría

## GUANTES

Nitrilo  
Látex  
Vinilo

## TEST

Anticuerpos IgG/IgM  
Antígenos Nasofaríngeo





# 3 LAYER SURGICAL MASK (Type IIR)



- 3 layer surgical mask Type IIR
- Polypropylene (PP) Covered Soft / Adjustable Nose
- Auricular Elastic
- CE mark, ISO, PLP



CODE	DESCRIPTION	PACKAGE
3LAYER	3 LAYER SURGICAL MASK IIR	50 pcs/pack

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class II)

## STANDARDS

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 9001:2000 Quality management systems. Requirements

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

EN 14683:2005 Surgical masks - Requirements and test methods

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

## OPTIONS

**COLORS** (more options available)





# 3 LAYER SURGICAL MASK KIDS (Type IIR)



- 3 layers kids mask
- 140 mm x 90 mm
- Polypropylene (PP) Covered Soft / Adjustable Nose
- Color White
- Auricular Elastic
- CE mark, ISO, PLP



CODE	DESCRIPTION	PACKAGE
3LAYERINF	3 LAYER KIDS MASK	10 packs*5 units – 50 pcs/pack

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class II)

## STANDARDS

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 9001:2000 Quality management systems. Requirements

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

EN 14683:2005 Surgical masks - Requirements and test methods

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements





# FFP2 Face Mask



- Protective Mask
- Particle filtering Half Mask
- Material: 33% PP Meltblown, 67% PP Spunbond, Goma, clip
- Clasification: FFP2 NR
- High Filtration Efficiency BFE>95%
- Auricular elastic band and secure foam nose pad
- 5 layers of filtration protection
- Suitable for sensitive skins
- Light and comfortable
- Single Use



CODE	DESCRIPTION	PACKAGE
FFP2	FFP2 Face Mask	Individual - 20 pcs/pack

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

2016/425/ECC EU Personal Protective Equipment Directive

## STANDARDS

EN 149:2001+A1:2009: Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes





## FFP2 Face Mask Kids



- Protective kids Mask
- Isolation protection
- Prevention of germs
- Breathable
- High Filtration Efficiency BFE > 95%
- Anti-fog / Dustproof
- 4 layers of filtration protection
- Suitable for sensitive skins
- Light and comfortable
- Single Use



CODE	DESCRIPTION	PACKAGE
FFP2INF	FFP2 CHILDREN MASK	10 pcs/pack

### DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

2016/425/ECC EU Personal Protective Equipment Directive

### STANDARDS

EN 149:2001+A1:2009: Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes







# FFP3 Face Mask



- Nowoven Spunbond and Meltblown Material
- FFP no valved, according to EN 149:2001
- High Filtration Efficiency BFE>99%
- Polypropylene
- Auricular elastic band and secure foam nose pad
- Glass fiber free
- Suitable for sensitive skins
- Light and comfortable
- Single Use



CODE	DESCRIPTION	PACKAGE
FFP3	FFP3 Face Mask	25 pcs/pack – 1.000 pcs/master

## DIRECTIVE

2016/425/ECC EU Personal Protective Equipment Directive

## STANDARDS

EN 149:2001+A1:2009: Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes





# Surgical Gown 25g



- Nowoven Spunbond Material 25 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BAT 25GR	Surgical Gown 25G	Individual – 125 units/master
BAT 25GREST	Surgical Gown 25G – Sterile	Individual – 125 units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL

**COLORS** (more options available)







# Surgical Gown 35g



- Nowoven Spunbond Material 35 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BAT35G	Surgical Gown 35g	Individual – 100 units/master
BAT35GREST	Surgical Gown 35g – Sterile	Individual – 100 units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)





# Surgical Gown 40g



- Nowoven Spunbond Material 40 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BAT40GR	Surgical Gown 40g	Individual – 80 units/master
BAT40GREST	Surgical Gown 40g Sterile	Individual – 80 units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)





# Surgical Gown 60g



- Nowoven Spunbond Material 60 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BAT60G	Surgical Gown 60g	Individual – 80 units/master
BAT60GREST	Surgical Gown 60g – Sterile	Individual – 80 units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)





# Laminated Surgical Gown 55g



- Nowoven Spunbond Material 40 gr/m<sup>2</sup> + 15 gr/ m<sup>2</sup> polyuretane Film
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BAT 7040LAM	Laminated Surgical Gown 55g	Individual – 80 units/master
BAT 7040LAMEST	Laminated Surgical Gown 55g Sterile	Individual – 80units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 14126 Performance Requirements and test methods for protective clothing against infective agents

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

COLORS (more options available)





# Laminated Surgical Gown 70g



- Nowoven Spunbond Material + polyuretane Film
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
7040LAM70	Laminated Surgical Gown 70g	Individual – 80 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

**EN 14126** Performance Requirements and test methods for protective clothing against infective agents

**EN 13795-1** Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

**EN 15223-1** Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

**EN ISO 14791** Medical Devices – Application of Risk Management to Medical Devices

**EN ISO 10993-1** Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)





# Reinforced Surgical Gown 40G



- Nowoven Spunbond Material 40gr + Reinforced PE
- With Reinforced PE at Front Side
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms



CODE	DESCRIPTION	PACKAGE
7040REF	Reinforced Surgical Gown 70g	Individual – 100 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

**EN 14126** Performance Requirements and test methods for protective clothing against infective agents

**EN 13795-1** Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

**EN 15223-1** Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

**EN ISO 14791** Medical Devices – Application of Risk Management to Medical Devices

**EN ISO 10993-1** Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)







# BAYMED SURGICAL GOWN 56g



- SMS + SB + PP Material
- Surgical Coat
- Waterproof, Breathable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Very comfortable to wear, good wet strength



CODE	DESCRIPTION	PACKAGE
BAYMED56	Baymed Surgical Gown 56g	Individual – 75 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

TS EN ISO 13485 MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM  
 TS EN ISO 9001:2015 QUALITY MANAGEMENT SYSTEM  
 TS EN ISO 15223-1 SYBOLS USED UN LABELING OF MEDICAL DEVICES  
 TS EN ISO 11135 STERILIZATION OF HEALTH MATERIALS – ETHLENE OXIDE  
 TS EN ISO 14971 APLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES  
 TS EN ISO 10993-1 BIOLOGICAL EVALUATION OF MEDICAL DEVICES  
 TS EN ISO 14664-1 PART 1: CLASSIFICATION OF AIR CLEANLESS  
 TS EN ISO 14644-2 PART 2: SPECIFICATIONS FOR TESTIN AND MONITORING TO PROVE CONTINUED COMPLIANCE WITH ISO 14644-1  
 TS EN ISO 14644-5 CLEAN ROOMS AND CONTROLLED ENVIROMENTS  
 TS EN ISO 13795-1 + A1 SURGICAL CLOTHING AND DRAPES – REQUIREMENTS AND TEST METHODS – PART 1. SURGICAL DRAPES AND GOWNS.  
 TSE EN 14126 – PROTECTIVE CLOTHING – PERFORMANCE REQUIREMENTS AND TEST METHODS FOR PROTECTIVE CLOTHING AGAINST INFECTIVE AGENTS  
 ISO 13934-1:2013 TEXTILES – TENSILE PROPERTIES OF FABRICS – PART 1  
 TS EN 1149-5 PROTECTIVE CLOTHING – ELECTROSTATIC PROPERTIES – PART 5  
 TS EN 1073-2 PROTECTIVE CLOTHING AGAINST RADIOACTIVE CONTAMINATION – PART 2  
 TS 391 EN ISO 9237 TEXTILES – DETERMINATION OF THE PERMEABILITY OF FABRICS TO AIR  
 TS 257 EN 20811/T1 TEXTILES FABRICS – DETERMINATION/RESISTANCE TO WATER PENETRATION – HYDROSTATIC PRESSURE TEST  
 ISO 5085-1 TEXTILES – DETERMINATION OF THERMAL RESISTANCE – PART 1: LOW TERMAL  
 93/68/ECC CE MARKING DIRECTIVE





# Short Sleeve Gown 35g



- Nowoven Spunbond Material 35 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt



CODE	DESCRIPTION	PACKAGE
BATSM	Short Sleeve Gown 35g	Individual – 100 units/master
BATSMEST	Short Sleeve Gown 35g – Sterile	Individual – 100 units/master - Sterile

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

S – M – L – XL – XXL

**COLORS** (more options available)





# Reusable Gown 120g



- Waterproff Reusable Gown 120 gr/m<sup>2</sup>
- Min 20 washes (at 60 degrees)
- Antiallergic, Air Permeable
- Poliéster 50% - Cotton 50%
- Shape: Long Sleeves, Zero Collar, Open Back Side, With Belt, Knitted Elastic On Arms

CE

CODE	DESCRIPTION	PACKAGE
BATAREU	Reusable Gown	Individual – 80 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 811:2018 Textiles – Determination of resistance to water penetration – Hydrostatic pressure test

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# PE GOWN 30 micron

**sebersan**<sup>®</sup>  
www.sebersan.com



- High Density Polyethylene PH-HD
- 30 micron
- Color Blue
- Does Not Contain Latex
- Single Use

**CE**

CODE	DESCRIPTION	PACKAGE
BATAPLAS	PE Gown 30 micron	Individual – 100 units/master

## TECHNICAL CHARACTERISTICS

High Density Polyethylene PH-HD

Soft material

30 micron double layer

Color Blue

Single use





# Nylon Apron 64 micron

**sebersan**<sup>®</sup>  
www.sebersan.com



CE

CODE	DESCRIPTION	PACKAGE
DEL64	Nylon Apron 64 micron	Individual – 100 units/master

## TECHNICAL CHARACTERISTICS

High Density Polyethylene PH-HD

Soft material

64 micron double layer

Color White

Single use

Mobile Dispensers Available





# Visitor Gown 30g



- Nowoven Spunbond Material 30 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Single Use
- Shape: Long Sleeves, Men Collar, Velcro Strips Front Side, Double Seam Elastic On Arms



CODE	DESCRIPTION	PACKAGE
BATV7050	Visitor Gown 30g	Individual – 100 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

M – L – XL

**COLORS** (more options available)



### PACKAGE

NON STERILE







# Nonwoven Piyama 40g



- Nonwoven Spunbond Material 40 gr/m<sup>2</sup>
- Overlock Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Suitable for Sterilization
- Single Use
- Shape: Shirt: Long Sleeves, Zero Collar, Velcro Strips Front Side, Double Seam Elastic On Wrist And Ankle,
- Pants: Elastic On Waist



CODE	DESCRIPTION	PACKAGE
PIJ7080	Nonwoven Piyama	Individual – 50 units/master

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### SIZES

M – L – XL

**COLORS** (more options available)



### PACKAGE

NON STERILE





# Coverall Cat. I



- Category I
- Polypropylene
- Helps protect against minimal risks, such as certain non-hazardous liquid splashes and dusts
- Elasticated waist, ankles, and wrists for a good fit and freedom of movement
- Colour: White
- Single Use



CODE	DESCRIPTION	PACKAGE
CATITS	Coverall Cat I– Size S	Individual – 50 units/master
CATITM	Coverall Cat I– Size M	Individual – 50 units/master
CATITL	Coverall Cat I– Size L	Individual – 50 units/master
CATITXL	Coverall Cat I– Size XL	Individual – 50 units/master
CATITXXL	Coverall Cat I– Size XXL	Individual – 50 units/master

## DIRECTIVE

89/686/ECC Personal Protective Equipment (Category I)

## STANDARDS

**EN 943-1:2015+A1:2019** Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols - Part 1: Performance requirements for Type 1 (gas-tight) chemical protective suits (Endorsed by Asociación Española de Normalización in June of 2019.)

**EN ISO 13688:2013** Protective clothing - General requirements (ISO 13688:2013) (Endorsed by AENOR in January of 2014.)





# Coverall Cat. III Type 5&6



- Chemical Protective Coverall
- Elasticated round head, waist, cuffs and ankles.
- Colour: White
- Single Use
- Microporous laminated non-woven overall with elasticated Hood.



CODE	DESCRIPTION	PACKAGE
CAT3TS	Coverall Cat III Type 5&6 – Size S	Individual – 100 units/master
CAT3TM	Coverall Cat III Type 5&6 – Size M	Individual – 100 units/master
CAT3TL	Coverall Cat III Type 5&6 – Size L	Individual – 100 units/master
CAT3TXL	Coverall Cat III Type 5&6 – Size XL	Individual – 100 units/master
CAT3TXXL	Coverall Cat III Type 5&6 – Size XXL	Individual – 100 units/master

## DIRECTIVE

89/686/ECC Personal Protective Equipment

## STANDARDS

EN ISO 13688:2013 Protective clothing - Requirements

EN ISO 13982 -1:2004+A1:2010 Type 5 Protective clothing for use against solid particulates Type 5

EN 13034:2005+a1:2009 Type 6 Protective clothing against liquid chemicals Type 6

EN 1073-2:2002 Protective clothing against radioactive contamination

EN 14126:2003+AC:2004 Protective clothing against infective agents Types 5,6

EN 14325:2004 Protective clothing against chemicals





# Coverall Cat. III Type 3B/4B



- Disposable protective coveralls designed to protect from high pressure liquid jets (Type 3), low pressure liquid sprays (Type 4), hazardous dusts (Type 5), and light liquid splashes (Type 6).
- Elasticated waist, ankles and wrists provide convenience and freedom of movements.
- Front zipper with storm flap for comfortable fitting and additional protection.
- Colour: White
- Single Use
- Low- linting properties and anti-static coating.



CODE	DESCRIPTION	PACKAGE
CAT3TS-3B4B	Coverall Cat III Type 3B/4B – Size S	Individual – 45 units/master
CAT3TM-3B4B	Coverall Cat III Type 3B/4B – Size M	Individual – 45 units/master
CAT3TL-3B4B	Coverall Cat III Type 3B/4B – Size L	Individual – 45 units/master
CAT3TXL-3B4B	Coverall Cat III Type 3B/4B – Size XL	Individual – 45 units/master
CAT3TXXL-3B4B	Coverall Cat III Type 3B/4B – Size XXL	Individual – 45 units/master

## DIRECTIVE

89/686/ECC Personal Protective Equipment (Category I)

## STANDARDS

**EN 14605: 2005+A1:2009** Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3)

**EN 14605:2005+A1:2009** Protective clothing against liquid chemicals - spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

**EN ISO 13982-1:2005/A1:2011** Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) - Amendment 1 (ISO 13982-1:2004/AM 1:2010)

**EN 13034:2005+A1:2009** Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)

**EN 14126:2004** Protective clothing - Performance requirements and tests methods for protective clothing against infective agents

**EN 1149-5: 2018** Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements (Endorsed by Asociación Española de Normalización in November of 2018.)





# Information

- Cat. I** Protección contra riesgos mínimos  
**Cat. II** Protección ante riesgos de grado medio o elevado  
**Cat. III** Protección ante riesgos mortales o irreversibles

EN14605



EN 14605:2005+A1:2009

**Ropa de protección contra productos químicos líquidos. Tipo 3**

Requisitos de prestaciones para la ropa con uniones herméticas a los líquidos (tipo 3)

EN14605



EN 14605:2005+A1:2009

**Ropa de protección contra productos químicos líquidos. Tipo 4**

Requisitos de prestaciones para la ropa con uniones herméticas a las pulverizaciones (tipo 4)

EN13982-1



EN ISO 13982-1:2005/A1:2011

**Ropa de protección contra partículas sólidas de productos químicos. Tipo 5**

Parte 1: Requisitos de prestaciones para la ropa de protección química que ofrece protección al cuerpo completo contra partículas sólidas suspendidas en el aire.

EN13034



EN 13034:2005+A1:2009

**Ropa de protección contra productos químicos líquidos. Tipo 6**

Requisitos de prestaciones para la ropa de protección química que ofrece protección limitada contra productos químicos líquidos.

EN1073-2



EN 1073-2:2003

**Ropas de protección contra la contaminación radioactiva.**

Parte 2: Requisitos y métodos de ensayo para la ropa de protección no ventilada contra la contaminación por partículas radioactivas.

EN14126



EN 14126:2004

**Ropas de protección.**

Requisitos y métodos de ensayo para la ropa de protección contra agentes biológicos.

EN1149-5



EN 1149-5:2018

**Ropas de protección. Propiedades electrostáticas.**

Parte 5: Requisitos de comportamiento de material y diseño.





# Surgical Caps



- Nowoven Spunbond Material 30 gr/m<sup>2</sup>
- Ultrasonic Seam
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
AMET6020	Surgical Cap With Tie	100 Pcs./Box, 1000 Pcs./Carton
AMET6030	Surgical Cap With Elastic	100 Pcs./Box, 1000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

**COLORS** (more options available)







# Bouffant Cap



- Nowoven Spunbond Material 15 gr/m<sup>2</sup>
- Ultrasonic Seam
- Double Seam Elastic
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
GOR100	Bouffant Cap	250 Pcs./Box, 1000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

**COLORS** (more options available)





# Cap Astronaut Type



- Nonwoven Spunbond Material
- Overlock Seam
- Head Wraps Completely and Comfortable Use
- Antiallergic, Air Permeable
- Does Not Contain Latex and Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
CAPAST	Cap Astronaut Type	100 Pcs./Box, 1000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

COLORS (more options available)





# Shoe Cover CPE



- 1st Quality Polyethylene (CPE) Material
- Anti-Slip Feature
- Liquid Proof
- Elastic
- Single Use



CODE	DESCRIPTION	PACKAGE
CAL100PE	Polyethylene Shoe Cover	100 Pcs./Box, 4000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Shoe Cover Nonwoven



- Nonwoven Spunbond Material 30gr/m<sup>2</sup>
- Anti-Slip Feature
- Ultrasonic Seam
- Double Seam Elastic
- Antiallergic, Air Permeable
- Does Not Contain Latex, Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
CAL100	Shoe Cover Nonwoven 30gr/m <sup>2</sup>	250 Pcs./Box, 1000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Boots Shoe Covers PE



- Polyethylene 120 micron
- Anti-Slip Feature
- Overlock Seam
- Double Seam Elastic
- Antiallergic
- Does not contain Latex and Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
BOOTCOVPE	Boots Shoe Cover Polyethylene	2.000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Boots Shoe Covers PP



- Nowoven Spunbond Material 40gr/m2
- Anti-Slip Feature
- Overlock Seam
- Double Seam Elastic
- Antiallergic, Air Permeable
- Does not contain Latex and Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
BOOTCOVPP	Boots Shoe Cover Polypropylene	2.000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Polyethylene Sleeve (PE)



- 1st Quality Polyethylene Material, Single Layer 20 micron
- Waterproof
- Elastic
- Single Use



CODE	DESCRIPTION	PACKAGE
MAN100	Polyethylene Sleeve	100 Piece/Pack, 2000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS







# Nonwoven Sleeve 25gr



- Nonwoven Spunbond Material 25 gr/m<sup>2</sup>
- Overlock Seam
- Gimped Elastic on Elbow
- Knitted Wrist
- Antiallergic, Air Permeable
- Does Not Contain Latex, Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
MAN100	Nonwoven 3010 Sleeve	100 Piece/Pack, 1.000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Nonwoven Sleeve Knitted 25gr



- Nonwoven Spunbond Material 25 gr/m<sup>2</sup>
- Overlock Seam
- Gimped Elastic and Knitted
- Knitted Wrist
- Antiallergic, Air Permeable
- Does Not Contain Latex, Fiberglass
- Single Use



CODE	DESCRIPTION	PACKAGE
MAN100	Nonwoven 3020 Sleeve	100 Piece/Pack, 1.000 Pcs./Carton

## DIRECTIVE

93/42/ECC Medical Device Regulation (Class I)

## STANDARDS

EN 13795-1 Surgical Clothing and Drapes – Requirements and Methods – Part 1: Surgical Drapes and Gowns

EN 15223-1 Medical Devices – Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements

EN ISO 14791 Medical Devices – Application of Risk Management to Medical Devices

EN ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

## OPTIONS

### COLORS





# Integral Safety Glasses



- Flexible PVC
- With a groove on its inside surface to hold the eyepiece
- With ventilation
- Panoramic (one piece)
- Anti-fog
- Anti-scratch
- Protection against static electricity

CE

CODE	DESCRIPTION	PACKAGE
CLI539	Integral Safety Glasses	8 pcs/pack

## STANDARDS

**EN166:2002** Personal eye-protection - Specifications.

**EN 1149-1** Protective clothing - Electrostatic properties - Part 1: Test method for measurement of surface resistivity

**EN 1149-5** Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements

**Health and safety requirements of R.D. 1407/1992**

**Control body number N°0530**





# Visitor Glasses



- EPI CAT. II
- Polycarbonate glasses
- Ergonomic
- With ventilation
- Anti-scratch
- Protection against ultraviolet UV filters



CODE	DESCRIPTION	PACKAGE
GAFVIS	Visitor Glasses	12 pcs/pack

## STANDARDS

**EN166:2002** Personal eye-protection - Specifications.

**EN 170:2003** Personal eye-protection - Ultraviolet filters - Transmittance requirements and recommended use.





# Face Shield



- Extra Comfortable Elastic Foam Band
- Anti-fog
- Impact&High temperatura resistant
- Lightweight and comfortable to wear, quick and easy to puto n
- Protect face from blood, body fluid sor harmful chemical splash

CE

CODE	DESCRIPTION	PACKAGE
VIS01	Face Shield	20 pcs/pack

## STANDARDS

EN166:2002 Personal eye-protection - Specifications.

Regulation EU 2016/425 on personal protective equipment and repealing Council Directive 89/686/EEC





# Hand Sanitizer 500 ml



- Hand Sanitizer 500 ml
- AEMPS Recomendado\* (Agencia Española de Medicamentos y Productos Sanitarios)
- Ph: 6,70 +- 0,30
- Alcohol: 75%
- Viscosity: 3.000 – 6.500 cps
- Benzalkonium Chloride: 1.000pm



CODE	DESCRIPTION	PACKAGE
GEL500	Hand Sanitizer 500 ml	12 pcs/box

## DIRECTIVE

Directive 98/8/CE concerning the placing of biocidal products on the market

## STANDARDS

**EN 1500:2013** Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)

**EN 12791:2006** Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

**EN 13624:2014** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)

**EN 13727:2012+A2:2015** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

**EN 14476:2014+A2:2020** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)





# Hand Sanitizer 5L



- AEMPS Recommended\* (Agencia Española de Medicamentos y Productos Sanitarios)
- Alcohol: 70%
- Citric Acid
- Benzalkonium Chloride



CODE	DESCRIPTION	PACKAGE
GEL5L	Hand Sanitizer 5 L	4 pcs/box 128 pcs/pallet

## DIRECTIVE

Directive 98/8/CE concerning the placing of biocidal products on the market

## STANDARDS

**EN 1500:2013** Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)

**EN 13624:2014** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)

**EN 13727:2012+A2:2015** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

**EN 14476:2014+A2:2020** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)







## Pulsera de gel Cleands



- Pulsera de Gel Hidroalcohólico
- Recargables
- Disponibles en varios colores
- Material hipoalergénico y biodegradable
- Ajustables
- Diseño moderno, ergonómico
- 100 % reciclable
- Fabricado en España



CODE	DESCRIPTION	PACKAGE
PULDOSGEL	Pulsera Dosificadora de Gel	24 Pcs./Box





# Basic Sanitizer Dispenser



- Basic Manual Sanitizer dispenser
- Locking safety design
- Unique Wall design
- Stainless
- High resistance

CE

CODE	DESCRIPTION	PACKAGE
BASICSAN	Basic Sanitizer Dispenser	1 pcs/pack

## STANDARDS

UNE-EN ISO 9001:2015 : Certification of a quality system based on UNE-EN ISO 9001:2008.





## Automatic Sanitizer Dispenser



- Touchless sanitizer dispenser
- Locking safety design
- Unique Wall design
- Stainless
- High resistance



CODE	DESCRIPTION	PACKAGE
AUT SOAP	Automatic Sanitizer Dispenser	1 pcs/pack

### STANDARDS

**UNE-EN ISO 9001:2015** : Certification of a quality system based on UNE-EN ISO 9001:2008.

**ISO 2859-1:1999** : Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection





# Surface Disinfectant 750ml



- AEMPS Recommended\* (Agencia Española de Medicamentos y Productos Sanitarios)



CODE	DESCRIPTION	PACKAGE
VIRU750ML	Surface Disinfectant 750 ML	4 pcs/box 128 pcs/pallet

## DIRECTIVE

Directive 98/8/CE concerning the placing of biocidal products on the market

## STANDARDS

**EN 13697:2015** Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)

**EN 14476:2014+A2:2020** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)





# Surface Disinfectant 5L



- AEMPS Recommended\* (Agencia Española de Medicamentos y Productos Sanitarios)



CODE	DESCRIPTION	PACKAGE
VIRU5L	Surface Disinfectant 5 L	4 pcs/box 128 pcs/pallet

## DIRECTIVE

Directive 98/8/CE concerning the placing of biocidal products on the market

## STANDARDS

**EN 13697:2015** Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)

**EN 14476:2014+A2:2020** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)





# Infrared Thermometer



- IR Temperature: 32°C – 42°C / 89°F – 108°F
- Accuracy +/- 0.4°C
- Resolution 0.1°C
- Spectral Response 8-14 um
- Measurement Distance 5-15 cm
- Ambient Operating 15°C-35°C
- Response Time approx 1s
- Relative Humidity 10%-90%
- LBD – Low Battery Display
- Power Supply 2 x 1.5AAA Battery
- Product Size 148mm x 95mm x 50mm
- Certificates CE, ROHS, ETL, FCC



CODE	DESCRIPTION	PACKAGE
TERINFR	Infrared Thermometer	40 pcs/pack

## DIRECTIVE

European Union's Directive 2011/65/EU and EU 2015/863

## STANDARDS

**EN61326-1:2013** Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (Endorsed by AENOR in March of 2013.)

**EN61326-2-3:2013** Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-3: Particular requirements - Test configuration, operational conditions and performance criteria for transducers with integrated or remote signal conditioning (Endorsed by AENOR in March of 2013.)



# Nitrile Gloves



- Powder free
- Latex free
- Disposable
- CE Compliant
- Figure Textured
- Single Use

EN ISO 374-5



VIRUS



CODE	DESCRIPTION	PACKAGE
NITS	Nitrile Gloves – Size S	100 units / box
NITM	Nitrile Gloves – Size M	100 units / box
NITL	Nitrile Gloves – Size L	100 units / box
NITXL	Nitrile Gloves – Size XL	100 units / box

## DIRECTIVE

**93/42/ECC** Medical Device Regulation (**Class I**)

**89/686/CEE** Personal Protective Equipment (**Cat III**)

## STANDARDS

**EN 374-5:2016** Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks (ISO 374-5:2016) (Endorsed by Asociación Española de Normalización in June of 2017.)

**EN 420:2004** Protective gloves - General requirements and test methods

**ISO 13485:2003**, Quality system for the healthcare products production.







# Latex Gloves



- Disposable Gloves
- Latex, strong quality
- Excellent Sense of touch for very precise working
- Very tearproof, extremely elastic and very resistant
- Considered as PPE for protection against solvents and chemicals
- Single Use



CODE	DESCRIPTION	PACKAGE
LATS	Latex Gloves – Size S	100 units / box
LATM	Latex Gloves – Size M	100 units / box
LATL	Latex Gloves – Size L	100 units / box
LATXL	Latex Gloves – Size XL	100 units / box

## DIRECTIVE

93/42/ECC Medical Device Regulation (Cat III)

## STANDARDS

**EN 374/5** Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks (ISO 374-5:2016) (Endorsed by Asociación Española de Normalización in June of 2017.)

**EN 420:2004** Protective gloves - General requirements and test methods

**EN 455 4** Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

**ISO 13485:2003**, Quality system for the healthcare products production.





# Vinyl Gloves



- Transparent vinyl gloves
- Smooth surface for greater sensitivity and beaded cuff
- Composition: Polyvinyl Chloride (PVC)
- Latex free
- Single Use



CODE	DESCRIPTION	PACKAGE
VIT S	Vinyl Gloves – Size S	100 units / box
VIT M	Vinyl Gloves – Size M	100 units / box
VIT L	Vinyl Gloves – Size L	100 units / box
VIT XL	Vinyl Gloves – Size XL	100 units / box

## DIRECTIVE

**93/42/ECC** Medical Device Regulation (**Class I**)

**89/686/CEE** Personal Protective Equipment (**Cat III**)

## STANDARDS

**EN 374/1-2-3** Protective gloves: Chemicals and Microorganisms permeation.

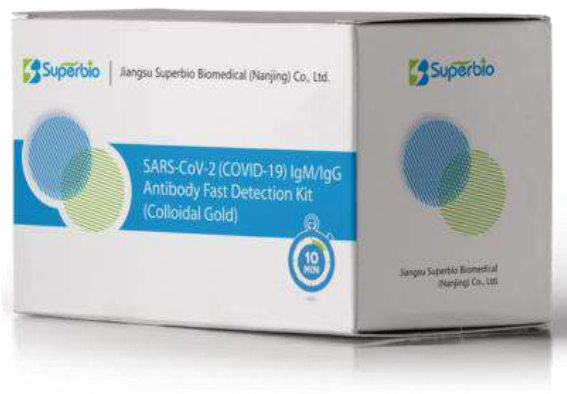
**EN 420:2004** Protective gloves - General requirements and test methods

**ISO 13485:2003**, Quality system for the healthcare products production.





# Fast COVID-19 IgM/IgG Antibody Detection Kit Superbio



- IVD test for IgM and IgG antibodies self-testing in blood.
- Based on fluorescent immunochromatography.
- The testing kit contains: 1) an antigen labelled by colloidal gold and a complex of control antibodies; 2) nitrocellulose membranes with two testing lines
- Developed and tested for blood samples testing by the general public.
- Test result after 3 minutes
- Specificity: 96,4%
- Sensibilidad: 99,7%



CODE	DESCRIPTION	PACKAGE
COV19-10	Fast COVID-19 IgM/IgG Antibody Detection Kit Superbio	20 test/box

## STANDARDS

**Directive 98/79/EC** of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

**EN ISO 13485:2016** Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

**EN ISO 15223-1: 2016** Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)

**EN ISO 14971: 2012** Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

**EN 13641: 2002** Elimination or reduction of risk of infection related to in vitro diagnostic reagents

**EN ISO 18113-1: 2011** Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

**EN ISO 18113-2: 2011** Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

**EN ISO 23640: 2015** Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)





## Fast COVID-19

# Antigen Rapid Test Cassette Biozek



- Rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens presents in human nasopharynx.
- Results are for the detection of SARS-CoV-2 Antigens.
- Result at 15 minutes. Do not interpret the result after 20 minutes.
- High accuracy.
- Diagnostic Specificity: 100%
- Diagnostic Sensitivity: 93,3%

CE

CODE	DESCRIPTION	PACKAGE
ANTITEST	Fast COVID-19 Antigen Rapid test Cassette Biozek	30 test/box

### STANDARDS

**Directive 98/79/EC** of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

**EN ISO 13485:2016** Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

**EN ISO 15223-1: 2016** Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)

**EN ISO 14971: 2012** Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

**EN 13641: 2002** Elimination or reduction of risk of infection related to in vitro diagnostic reagents

**EN ISO 18113-1: 2011** Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

**EN ISO 18113-2: 2011** Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

**EN ISO 23640: 2015** Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

