



THE NEXT GENERATION OF HEALTHCARE SOLUTIONS

• **2021 - 2022**

Health Care Product Catalog



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About Us

SipaMED, extends from one mission, to make healthcare better for the next generation of people. SipaMED is a high-tech manufacturing and distribution company specialized in R&D and the production and distribution of medical consumables, professional protection equipment and durable medical equipment with the most advanced equipment and technology.

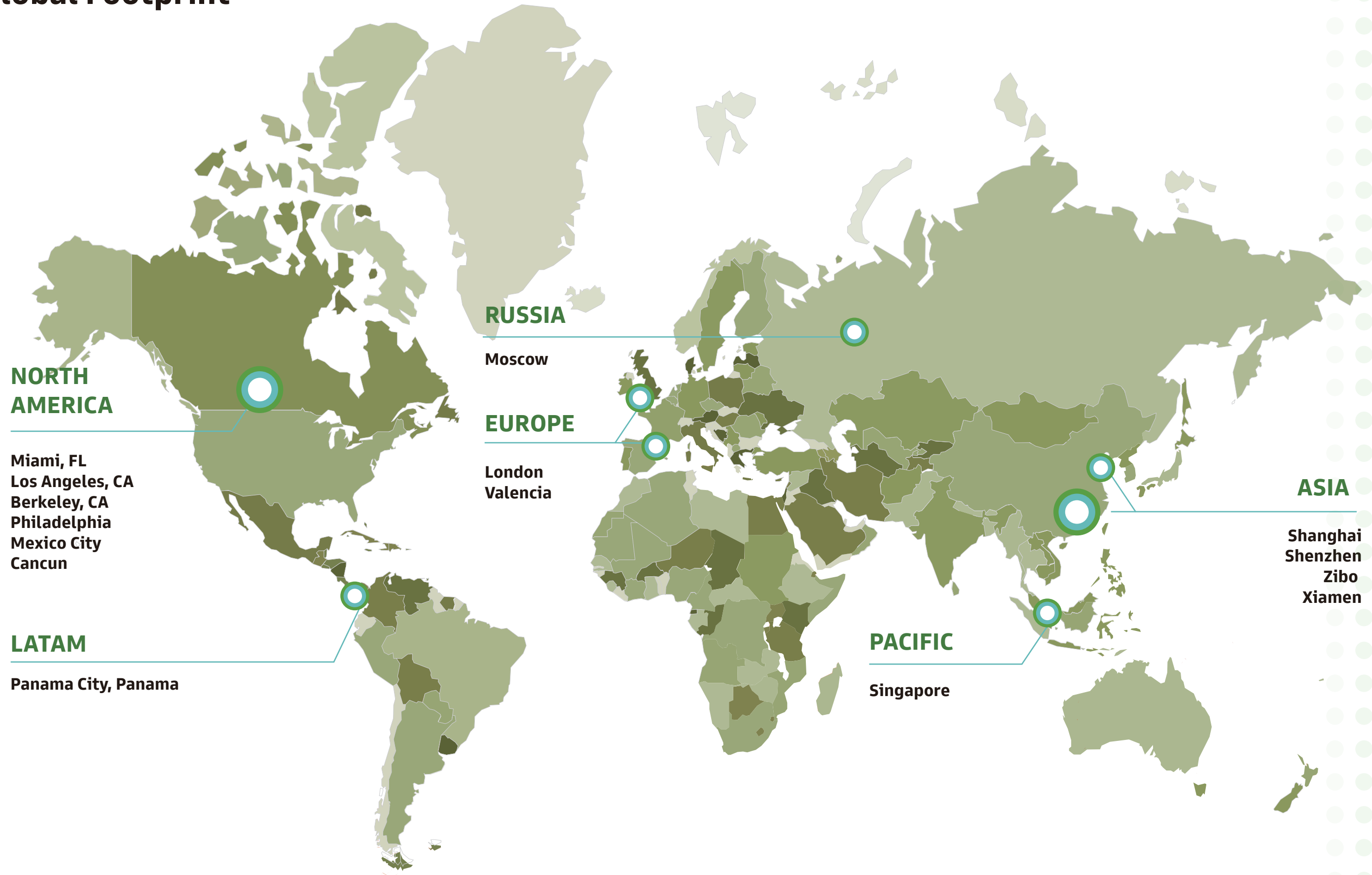
In an ever-changing global market filled with uncertainty and shortages, SipaMED is more than a manufacturer and distributor, establishing one of the most dependable manufacturing and logistics operations in the market to help your business achieve your long-term goals and optimize performance.

Our team has over 30+ years' expertise in the areas of production, logistics, supply chain management and finance in order to bring SipaMED and our brand Sipa™ to the forefront of the global market. We work as an extension of your team, sharing our expertise across industries to solve problems together and provide 360 solutions that help healthcare systems and facilities across the spectrum the supply chain resources they need to deliver their best care.

Committed to your business, to help you optimize performance.











● Global Footprint



● Choosing the Right Glove

Choosing the correct gloves to provide the protection and dexterity for a specific task is not always straightforward. We have therefore created the following table to summarize the differences between the main glove material types.

Range Performance Chart

Properties	Latex	Nitrile	Nitrile Blend	Vinyl
 Toughness & Durability	★★★★	★★★★	★★★	★★★★
 Grip	★★★★	★★★	★★	★★
 Sensitivity & Tactility	★★★★	★★★	★★	★
 Comfort, Fit & Dexterity	★★★★	★★★	★★	★★
 Chemical Resistance	★★★	★★★★	★★	★
 Barrier Performance	★★★★	★★★★	★★★	★★
 Tear Resistance	★★★★	★★★	★★	★★
 Food Contact	★★★	★★★★	★★★	★★

Rating ★ Fair ★★ Good ★★★ Very Good ★★★★ Excellent

Approximate ratings are relative and for guidance only.



Toughness & Durability

It is essential that gloves retain their integrity and resist tearing both when donning and in use. Nitrile and latex gloves are naturally more durable in use and less likely to rip on donning than vinyl gloves – even though they can be thinner than vinyl. This is due to the superior material characteristics.



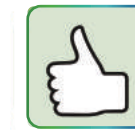
Grip

The requirement for grip varies with the task being performed. For example, when manipulating a surgical instrument, a firm and reliable grip is critical. When caring for the elderly and patient bathing, a high level of grip is undesirable as it can cause discomfort or damage to the skin. The level of grip offered by a glove is dependent on the molecular structure of the material and whether the surface has a texture applied. Texture helps provide wet grip. Latex offers the maximum grip, as it is naturally 'grippy' material. Nitrile gloves are less grippy than latex and the fingertips only are textured. They provide an intermediate level of grip suitable for most tasks. Finally, vinyl is naturally smooth and silky, with no added texturing so it has the lowest grip of the material types - making Vinyl the gloves of choice for patient comfort, particularly in the care of the elderly.



Sensitivity & Tactility

Sensitivity of touch is needed if handling small objects, holding delicate items, feeling for veins when inserting a cannula or taking blood, etc. Latex are the best gloves for sensitivity as they are very close fitting and very stretchy. Thin nitrile offers slightly less sensitivity than latex but are still very good. Vinyl gloves, in comparison offer low sensitivity.



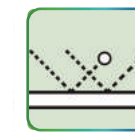
Comfort, Fit & Dexterity

The more stretch a glove has, the better it will conform to your hand and the less effort it will take to move the hand and fingers – thus reducing hand fatigue and increasing both dexterity and comfort levels. Latex offers the highest stretch, dexterity, and comfort, closely followed by thin wall nitrile. Vinyl gloves have much lower levels of stretch – though the range includes a synthetic vinyl which offers more stretch and comfort than standard vinyl. Latex gloves are quite tolerant when trying to don too small a glove – as they stretch to fit the hand. Nitrile, being a bit less stretchy, are slightly less tolerant, and vinyl gloves really need to be the correct size for the hand – and may require a larger size to prevent ripping on donning.



Chemical Resistance

The latex, nitrile and vinyl gloves are medical examination gloves and in general are not specifically for use with aggressive chemicals. However, they are resistant to a wide range of chemicals – each material type having different resistance characteristics. Nitrile has a very broad spectrum of chemical resistance - latex less so as it can break down if certain oil-based products come into contact with it. Sipa gloves have been extensively tested and are certified as complex PPE for handling potentially dangerous chemicals. They exhibit excellent chemical resistance, in particular, to aggressive chemotherapy drugs. Before using a glove with chemicals, a risk assessment should be undertaken, and the glove chosen which provides protection from the chemical of interest. Generally, vinyl gloves offer the least chemical resistance but are suitable for use with diluted detergent solutions for cleaning.



Barrier Performance

Medical examination gloves protect both the wearer and the patient against cross infection risk. Latex and nitrile gloves have exceptionally high biological barrier characteristics. In addition, the more durable a glove, the less likely it is to tear – and a torn glove offers no barrier protection at all! Nitrile and latex gloves have excellent durability. Vinyl gloves offer much lower barrier protection due to their material composition and lower durability – so they are suitable for lower risk clinical tasks only.



Tear Resistance

Tearing occurs typically on donning and in use. On donning, gloves can tear at the cuff. Latex and nitrile gloves offer excellent performance against cuff tearing as they are very stretchy. Vinyl gloves are more prone to tearing, particularly if they are a tight fit or pulled on too roughly. Tearing can also occur in use – usually when the material is punctured or snagged. Latex and nitrile are both very resistant. In particular, Nitrile has a very high puncture resistance though once punctured tears quickly. Vinyl is the most likely to tear in use. In addition to these material differences, the thicker the glove within a material type, the better the tear resistance. Note that long fingernails and rings can cause gloves to tear.

● Choosing the Right Glove



Latex Allergy Risk

Certain individuals may be sensitive to the proteins found in natural rubber latex. This can cause effects ranging from mild skin irritation to a severe allergic reaction known as a Type I natural rubber latex allergic reaction. This is caused when the latex proteins come into contact directly with the skin or mucous tissue, or alternatively when the proteins are carried in the air – usually attached to glove powder. Although it seems an obvious point, only latex gloves contain natural rubber latex proteins. Nitrile and vinyl are latex free. Latex gloves are specially treated to minimize the free latex proteins, though use by sensitive individuals should be avoided. Products containing natural rubber latex are marked on the carton with the symbol displayed on the left.



Contact Dermatitis Risk

Many people believe that if they choose nitrile or vinyl gloves, but they can avoid skin reactions – but that is not true. They can avoid a natural rubber latex allergic reaction as there is no latex in these gloves, but they can suffer from contact dermatitis. This is caused by sensitivity to free chemicals in the gloves, typically Sulphur and accelerators used in nitrile gloves – known as a Type IV Chemical Allergy. The chemistry used in Sipa gloves is highly advanced with extremely low levels of sensitizing chemicals.



Ease of Donning

Gloves can be difficult to don, particularly if the hands are wet or the glove is too small. All latex and nitrile gloves are specially treated inside to ease the donning process. Vinyl are not treated – though the fact that they are normally worn baggy and that they are naturally slippery helps donning.



Powder Content

None of the Sipa in this catalogue are powdered. This is because they are specially manufactured so that powder is not needed to aid donning. In addition, powder can leave an unpleasant residue on the hand after use (it combines with sweat) and it can cause natural rubber latex proteins to become airborne if they combine with the powder.



Food Contact

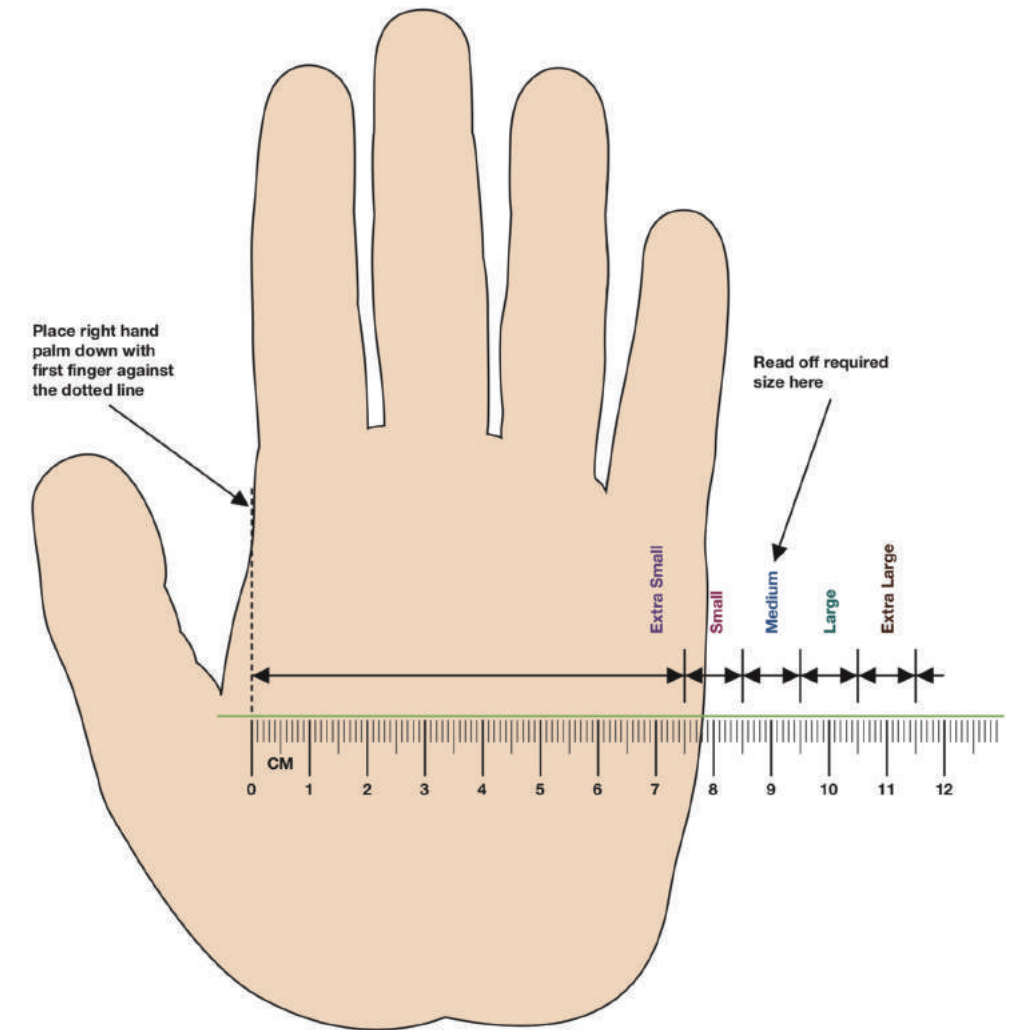
When handling food, it is very important that chemicals in the glove do not leach out and get onto the food where they could be ingested. The food itself can trigger the release of these chemicals – depending on the glove material type. Latex and nitrile gloves are approved for contact with all types of food. Vinyl gloves are frequently used for food preparation, but nearly all types are only suitable for safe use with non-fatty foods - and most foods are fatty.

Glove Size Guide

This sizing chart is provided for guidance only. Actual fit varies - depending on the material and thickness (weight and hand shape). To determine the most suitable size for any particular range of gloves, we recommend that you trial samples of 2 or more sizes.

Step-By-Step Glove Sizing Process

1. Measure around. Wrap a fabric tape measure around the widest part of your hand. When measuring for glove size, you should always use your dominant hand — your right hand if you're right-handed and left if left-handed. The tape measure should wrap over the top of your hand and across your palm at its widest point. Record the size of your hand at this point in inches.
2. Measure lengthwise. Once you've measured around, it's time to measure lengthwise. Spread your hand and fingers and place the tape measure at the tip of your middle finger. Then stretch the tape measure down to the base of your hand, holding it taut where your wrist begins. Again, record the length of your hand at this point in inches.
3. Choose the larger number and round up. Now you have two figures in inches. It's time to choose the larger figure and round up. For example, the measurement around your hand may be 5½ inches, and the lengthwise measurement of your hand may be 6¾ inches. In this case, you would take the 6¾ figure and round up to 7. That means your glove size is a 7.



● Hand Protection

01 Nitrile Blend

04 Latex

07 Surgical

02 Nitrile

05 Industrial

03 Vinyl

06 Nitrile Extended Cuff



Nitrile Blend

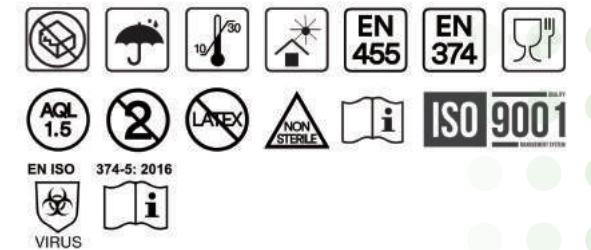
9901

SIPA™ nitrile blend examination glove is no ordinary glove. It provides the latest thin wall nitrile technology without compromising strength. With innovation in a high-performance formula, this medical-grade glove gives you ultra-comfort, superb sensitivity, and all-condition toughness.

- **Premium Quality** - laboratory-proven formula and advanced manufacturing using ultra-pure materials
- **Superior biological and chemical resistance** - protection against a wide range of hospital and laboratory chemicals
- **Suitable for laboratory and PPE use** - independently credited design and production
- **Powder-free** - for best hygiene
- **Lightweight construction** - for high sensitivity
- **High stretch** - for premier comfort and fit
- **Easy donning** - for speed and convenience
- **Food contact approved** - safe for use with all types
- **Color** - ocean blue

SIPA™ nitrile blend examination glove is the optimum solution for high volume nitrile glove requirements in acute and community healthcare settings, and is also well-suited to a wide range of cleaning, general industrial or home tasks.

Technical Performance	
Classification	Single-use medical examination glove Class I Medical Device, Non-sterile, Powder-free
Approval	FDA 510(K), LZA
Design	Ambidextrous
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM D6319, BS EN 455, Parts 1, 2, 3, and 4. Medical gloves for single-use - Minimum force at break - 9 Newtons before aging, 7 Newtons after aging - Tensile strength - 21 MPa before aging, 17 MPa after aging - Elongation at break - 500% before aging, 400% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - Simple design - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 240 mm in length - Thickness (single wall) - Palm 0.10 mm - Finger 0.10-0.12 mm - Width across palm - Small - 82-85 mm - Medium - 92-95 mm - Large - 103-106 mm - X-Large - 112-115 mm
Applications	Clinical procedures and routine tasks, medical applications, emergency services, community nursing, nursing homes, care homes, cleaning - clinical and general, local authority, police, customs, education, light industrial use, motor industry, food catering, general use



Nitrile

9903

SIPA™ nitrile examination glove is the future of chemo-rated medical gloves. For years, scientists at SipaMED labs have been pushing the boundaries of an advanced nitrile formula, and now the future has arrived. With its astonishing performance, SIPA™ nitrile glove is the chemo-rated nitrile glove that replaces all nitrile gloves.

- **Industry-leading technology** - breakthrough in formula offers unparalleled performance
- **Supreme quality** - free from latex, ultra-low dermatitis risk and zero natural rubber latex allergy risk
- **High Chemotherapy drug resistance** - Tested protection for safety in use
- **Powder-free** - for best hygiene
- **Lightweight construction** - for high sensitivity
- **High stretch** - for premier comfort and fit
- **Finger and palm textured** - suitable for multiple tasks
- **Food contact approved** - safe for use with all types
- **Color** - ocean blue

SIPA™ nitrile is latex free, which eliminates the risk of a Type I natural rubber latex allergic reaction.

Technical Performance	
Classification	Single-use medical examination glove Class I Medical Device, Non-sterile, Powder-free
Approval	FDA 510(K), LZA
Design	Ambidextrous
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM D6319, BS EN 455, Parts 1, 2, 3, and 4. Medical gloves for single-use - Minimum force at break - 8.5 Newtons before aging, 7.5 Newtons after aging - Tensile strength - 18.5 MPa before aging, 18 MPa after aging - Elongation at break - 750% before aging, 700% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - ASTM D6978-5. Chemo-Rated BS EN 420. Protective gloves - general requirements and test methods - Gloves are 240 mm in length - Thickness (single wall) <ul style="list-style-type: none"> Palm 0.10-0.11 mm Finger 0.10-0.11 mm - Width across palm <ul style="list-style-type: none"> Small - 82-85 mm Medium - 92-95 mm Large - 103-106 mm X-Large - 112-115 mm
Applications	<p>Specialist applications</p> <p>Hospital clinical procedures, including administration of chemotherapy drugs or handling chemicals, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



Vinyl

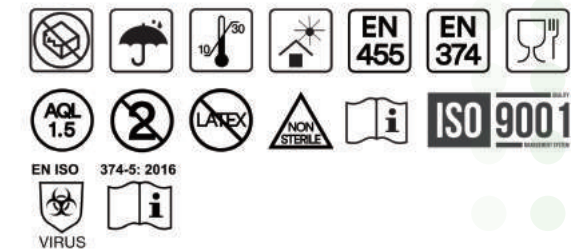
9904

SIPA™ vinyl examination glove utilizes a proven advanced formula which significantly improves the stretch and strength properties compared to ordinary vinyl gloves. SIPA™ vinyl is a high-quality and durable alternative to the large number of inferior vinyl gloves.

- **Material Purity** - free from latex, Sulphur and accelerators, ultra-low dermatitis risk and zero natural rubber latex allergy risk
- **Proven quality** - decades of supplying care homes and nursery in 30+ countries, widely accepted by health care professionals and elderly patients
- **Powder-free** - for best hygiene
- **Heavyweight construction** - for lasting durability
- **Good stretch** - for better comfort and fit
- **Food contact approved** - safe for use with all types
- **Color** - ocean blue

SIPA™ vinyl examination glove is best described as a glove which has a performance mid-way between the lower performing vinyl in the market and the higher performing nitrile. It is ideal for low risk clinical and general tasks where low grip is desirable (handling frail skin and hair) and where a relatively affordable and comfortable low cost glove is required.

Technical Performance	
Classification	Single-use medical examination glove Class I Medical Device, Non-sterile, Powder-free
Approval	FDA 510(K), LYZ
Design	Ambidextrous
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM D6319, BS EN 455, Parts 1, 2, 3, and 4. Medical gloves for single-use - Minimum force at break - 10 Newtons before aging, 8 Newtons after aging - Tensile strength - 20 MPa before aging, 17 MPa after aging - Elongation at break - 480% before aging, 400% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - Simple design - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 240 mm in length - Thickness (single wall) <ul style="list-style-type: none"> Palm 0.08-0.12 mm Finger 0.10-0.14 mm - Width across palm <ul style="list-style-type: none"> Small - 82-85 mm Medium - 92-95 mm Large - 103-106 mm X-Large - 112-115 mm
Applications	Clinical procedures and routine tasks, medical applications, emergency services, community nursing, nursing homes, care homes, cleaning - clinical and general, local authority, police, customs, education, light industrial use, motor industry, food catering, general use



Latex

9906

SIPA™ latex examination glove is designed for increased sensitivity of touch and comfort. SIPA™ latex examination glove delivers outstanding performance in the critical areas of barrier protection, grip, comfort, sensitivity of touch, tactility and feel. The gold standard for medical examinations, SIPA™ latex examination gloves are manufactured from heavy gauge latex and stringently tested to ensure the highest level of quality, every time.

- **Contains natural rubber latex** - pristine natural materials
- **Advanced manufacturing** - minimizes free natural latex proteins
- **High Biological resistance** - for best protection
- **Powder-free** - for best hygiene
- **Heavyweight construction** - high grade latex provides maximum sensitivity
- **Ultimate stretch** - for ultimate comfort and fit
- **Ultimate grip** - micro textured and grips even when wet
- **Food contact approved** - safe for use with all food types
- **Color** - ocean blue

SIPA™ latex examination glove offers very good microbiological barrier performance though limited chemical resistance. The advanced production process reduces free latex proteins to an absolute minimum, though if you have a known natural rubber latex allergy, we recommend you choose our SIPA™ nitrile examination glove.

Technical Performance	
Classification	Single-use medical examination glove Class I Medical Device, Non-sterile, Powder-free
Approval	FDA 510(K), LYY
Design	Ambidextrous
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM D6319, BS EN 455, Parts 1, 2, 3, and 4. Medical gloves for single-use - Minimum force at break - 8.5 Newtons before aging, 7.5 Newtons after aging - Tensile strength - 20 MPa before aging, 18 MPa after aging - Elongation at break - 1148% before aging, 797% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - ASTM D3578-10, ASTM D5151-11, ASTM D6124-11 - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 240 mm in length - Thickness (single wall) - Palm 0.09-0.12 mm - Finger 0.09-0.12 mm - Width across palm - Small - 80-84 mm - Medium - 93-97 mm - Large - 107-109 mm
Applications	<p>Specialist applications</p> <p>Hospital clinical procedures, including administration of chemotherapy drugs or handling chemicals, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



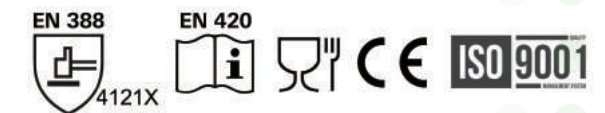
Industrial

9907

SIPA™ Nitrile Industrial gloves provide extreme durability for extended wear in abrasive applications.

- **Improved abrasion protection** - provides 20% more abrasion for longer lasting handling in abrasive conditions than regular industrial gloves
- **Enhanced grip** - up to 2 times more grip in dry environments for secure handling and a safer day at work
- **Signature nitrile coating** - the new and improved coating is softer which increases flexibility and comfort. The 1.25 mm nitrile coating provides up to 2 times more grip and offers 20% longer wear time.
- **Ergonomic fit** - Optimized knitting at the base of the pinky finger across the fingertips and through the palm matches natural hand contours
- **Ultimate comfort** - Enhanced the knitting in selecting zones of the liner improving support, breathability and range of movement
- **Silicone and Latex free** - no transfer of silicone and latex contaminants to metal parts prior to painting
- **Clean and skin friendly** - benefits from proprietary washing process that efficiently extracts impurities to deliver a cleaner, more comfortable glove
- **Color** - black on black, black on grey

Technical Performance	
Classification	13 Gauge Polyester Knitted Nitrile Coated Work Safety/Industrial Gloves
Approval	CE, ISO 9001
Design	Industrial
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Personal Protection Equipment Directive Category II</p> <ul style="list-style-type: none"> - EN 420: 2003+A1:2009 - Dexterity - 5 - Material Composition - Palm - nitrile-coated polyester, 350g/m2 - Back - polyester, 150g/m2 - Cuff - polyester/Elastic, 250g/m2 - Binding - polyester, black/brown/blue/red/yellow - Comply with Annex XVII of Reach Regulation (no 1907/2006 and revisions) 400% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - Simple design - EN 388: 2016: 4121X - Protective gloves - general requirements and test methods - Abrasion Resistance - 4 - Blade Cut Resistance - 1 - Tear Strength Resistance - 2 - Puncture Resistance - 1 - Cut Resistance Method (EN ISO 13997) - X - Minimum Length - 7/Small - 230 mm - 8/Medium - 240 mm - 9/Large - 250 mm - 10/X-Large - 260 mm - 11/XX-Large - 270 mm
Packaging	- 12 pairs in a bag - 12 bags in a carton
Applications	<p>Industries</p> <p>Aerospace, Automotive, Machinery and Equipment, Metal Fabrication</p> <p>General applications</p> <p>Assembly of small parts, General handling, Raw material handling, Picking and fastening components, Adjusting systems and screwing</p>



Nitrile Extended Cuff

9905-1/2/3

SIPA™ nitrile extended cuff examination glove is part of our SIPA™ specialty portfolio. They are best utilized in high-risk areas where additional protection is needed. It features a long, beaded cuff that safeguards the hands and wrist against spills and splashes while inhibiting roll down.

- **Supreme quality** - free from latex, ultra-low dermatitis risk and zero natural rubber latex allergy risk
- **High Chemotherapy drug resistance** - tested for use with various lab chemicals and chemotherapy drugs
- **Maximum biological and chemical resistance** - protection against a wide range of hospital and laboratory chemicals
- **Ultimate protection** - available in 12", 16", 19"
- **Powder-free** - for best hygiene
- **Lightweight construction** - for high sensitivity
- **High stretch** - for premier comfort and fit
- **Finger and palm textured** - suitable for multiple tasks
- **Food contact approved** - safe for use with all types
- **Color** - ocean blue

SIPA™ nitrile extended cuff glove is made of slightly thicker material. Designed with a special nitrile formulation, the glove feels and fits like latex allowing full range of motion and excellent flexibility to minimize hand stress and fatigue. Micro-textured fingertips provide a secure grip in wet and dry conditions. Full-textured version is also available upon request.

Technical Performance	
Classification	Single-use medical examination glove Class I Medical Device, Non-sterile, Powder-free
Approval	FDA 510(K), LZA
Design	Ambidextrous
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM D6319, BS EN 455, Parts 1, 2, 3, and 4. Medical gloves for single-use - Minimum force at break - 9 Newtons before aging, 8 Newtons after aging - Tensile strength - 22 MPa before aging, 18 MPa after aging - Elongation at break - 600% before aging, 550% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - ASTM D6978-5. Chemo-Rated - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 240 mm in length - Thickness (single wall) <ul style="list-style-type: none"> - Palm 0.11-0.13 mm - Finger 0.11-0.12 mm - Width across palm <ul style="list-style-type: none"> - Small - 82-85 mm - Medium - 92-95 mm - Large - 103-106 mm - X-Large - 112-115 mm
Applications	<p>Specialist applications</p> <p>Hospital clinical procedures, including administration of chemotherapy drugs or handling chemicals, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



Surgical Gloves - Nitrile, Sterile

9910

SIPA™ nitrile surgical glove is designed for the operating room professionals. With its outstanding performance, SIPA™ nitrile surgical glove is the surgical glove that replaces all gloves.

- **Industry-leading technology** - breakthrough in formula offers unparalleled performance
- **Sterile packaging** - free from contamination
- **Supreme quality** - free from latex, ultra-low dermatitis risk and zero natural rubber latex allergy risk
- **Powder-free** - for best hygiene
- **High stretch** - for premier comfort and fit
- **Ultimate grip** - micro-textured and grips even when wet
- **Finger textured** - suitable for multiple tasks
- **Color** - arctic blue

Maintaining a clean and sterile operating room is very important for infection control and successful results. Surgeons and the surgical team take extra measures to ensure a sterile operating room and their apparel is sterile. Surgical gloves are vital to maintaining infection control and a sterile surgical procedure site. SIPA™ surgical gloves are packed in sterile pairs providing the surgeon and surgical team with unexposed, sterile gloves for the procedure.

Technical Performance	
Classification	Single-use Surgeon's Gloves, Class I Medical Device, Sterile, Powder Free
Approval	FDA 510(K), KGO
Design	Sterile Independent Packaging
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM 3577-09, ISO 10993-10: 2010, ISO 11137-1: 2006 - Tensile strength - 23 MPa before aging, 17 MPa after aging - Elongation at break - 775% before aging, 650% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - ASTM D5151-11, ASTM D6124-11, ASTM D5712-10, ASTM D6499-12 - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 265 mm in length - Thickness (single wall) - Palm 0.10-0.12 mm - Finger 0.10-0.12 mm - Width across palm - 6.0 - 76-81 mm - 6.5 - 81-87 mm - 7.0 - 87-93 mm - 7.5 - 99-101 mm - 8.0 - 100-104 mm - 8.5 - 106-110 mm - 9.0 - 111-115 mm
Applications	<p>Specialist applications</p> <p>Hospital clinical procedures, including administration of chemotherapy drugs or handling chemicals, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



Surgical Gloves - Latex, Sterile

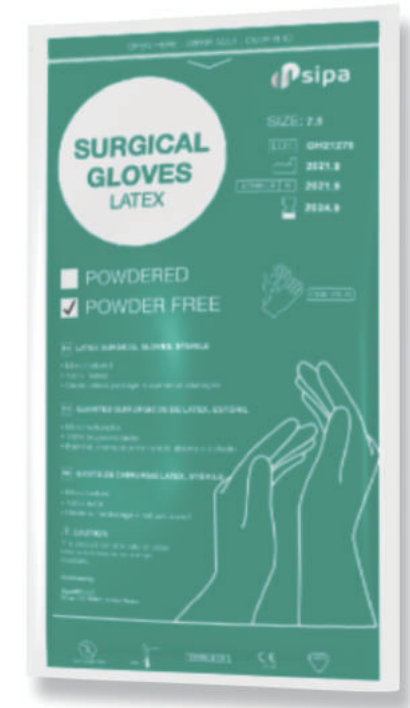
9909

SIPA™ latex surgical glove is designed for the operating room professionals. SIPA™ latex surgical glove delivers outstanding performance in the critical areas of barrier protection, grip, comfort, sensitivity of touch, tactility and feel.

- **Contains natural rubber latex** - pristine natural materials
- **Sterile packaging** - free from contamination
- **Advanced manufacturing** - minimizes free natural latex proteins
- **Powder-free** - for best hygiene
- **Heavyweight construction** - high-grade latex provides maximum sensitivity
- **Ultimate stretch** - for ultimate comfort and fit
- **Ultimate grip** - micro-textured and grips even when wet
- **Color** - creamy white

Maintaining a clean and sterile operating room is very important for infection control and successful results. Surgeons and the surgical team take extra measures to ensure a sterile operating room and their apparel is sterile. Surgical gloves are vital to maintaining infection control and a sterile surgical procedure site. SIPA™ surgical gloves are packed in sterile pairs providing the surgeon and surgical team with unexposed, sterile gloves for the procedure.

Technical Performance	
Classification	Single-use Surgeon's Gloves, Class I Medical Device, Sterile, Powder Free
Approval	FDA 510(K), KGO
Design	Sterile Independent Packaging
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Device Directives 93/42/EEC</p> <ul style="list-style-type: none"> - ASTM 3577-09, ISO 10993-10: 2010, ISO 11137-1: 2006 - Tensile strength 32.4 MPa before aging, 24.1 MPa after aging - Elongation at break - 1135% before aging, 932% after aging <p>Personal Protection Equipment Directive 89/686/EEC</p> <ul style="list-style-type: none"> - ASTM D5151-11, ASTM D6124-11, ASTM D5712-10, ASTM D6499-12 - BS EN 420. Protective gloves - general requirements and test methods - Gloves are 270-280 mm in length - - Thickness (single wall) - Palm 0.10-0.13 mm - Finger 0.10-0.13 mm - Width across palm - 6.0 - 76-81 mm - 6.5 - 81-87 mm - 7.0 - 87-93 mm - 7.5 - 99-101 mm - 8.0 - 100-104 mm - 8.5 - 106-110 mm - 9.0 - 111-115 mm
Applications	<p>Specialist applications</p> <p>Hospital clinical procedures, including administration of chemotherapy drugs or handling chemicals, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



● Respiratory Protection

01 Level I

03 KN95

02 Level III

04 N95



Disposable Surgical 3-Ply Mask

9921/9922

SIPA™ disposable surgical mask is the future of medical protection masks. For years, scientists at SipaMED labs have been pushing the boundaries of an advanced formula that offers more comfort and protection for healthcare professionals, and now the future has arrived. With its astonishing performance, SIPA™ disposable surgical mask is the mask that replaces all medical masks.

- **Premium Quality** - laboratory-proven formula and advanced manufacturing using ultra-pure materials
- **Superior biological and chemical resistance** - protection against a wide range of hospital and laboratory chemicals
- **Suitable for laboratory and PPE use** - independently credited design and production
- **Powder-free** - for best hygiene
- **Lightweight construction** - for high sensitivity
- **High stretch** - for premier comfort and fit
- **Easy donning** - for speed and convenience
- **Food contact approved** - safe for use with all types
- **Color** - ocean blue

SIPA™ disposable surgical mask is latex free, which eliminates the risk of a Type I natural rubber latex allergic reaction.

Technical Performance	
Classification	Single-use medical face mask, Class I Medical Device, Non-sterile, Latex-free
Approval	FDA Registration, CE Registration
Design	3-Ply with Ear-loops
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>Medical Devices Directives, Class I, Rule I, Annex VIII of MDR</p> <ul style="list-style-type: none"> - EN ISO 10993: 2018, Parts 1, 5, 10 - EN 149: 2001 + A1:2009 - EN 1041: 2008 - EN: 9072-15-2008 - EN 14683: 2019 + AC, TYPE I, TYPE II - EN 14971: 2019 - EN 15223-1: 2016 - EN 29073-1: 1992 <p>Personal Protection Equipment Directive FFP2 Approved</p> <ul style="list-style-type: none"> - 4D design - GB/T 19001-2016/ISO 9001: 2015 - YY/0469-2011 - YY/T0969-201
Dimensions	<p>Conform to CE standards</p> <ul style="list-style-type: none"> - Single mask 17.5 x 9.5 CM - 1 box of 50 masks, 20 x 10 x 8 CM - 1 carton of 40 boxes or 2,000 masks, 52 x 42 x 34 CM1
Applications	<p>Specialist applications Hospital clinical procedures, contact with high risks patients (viral infection risk), laboratory use</p> <p>General applications Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>

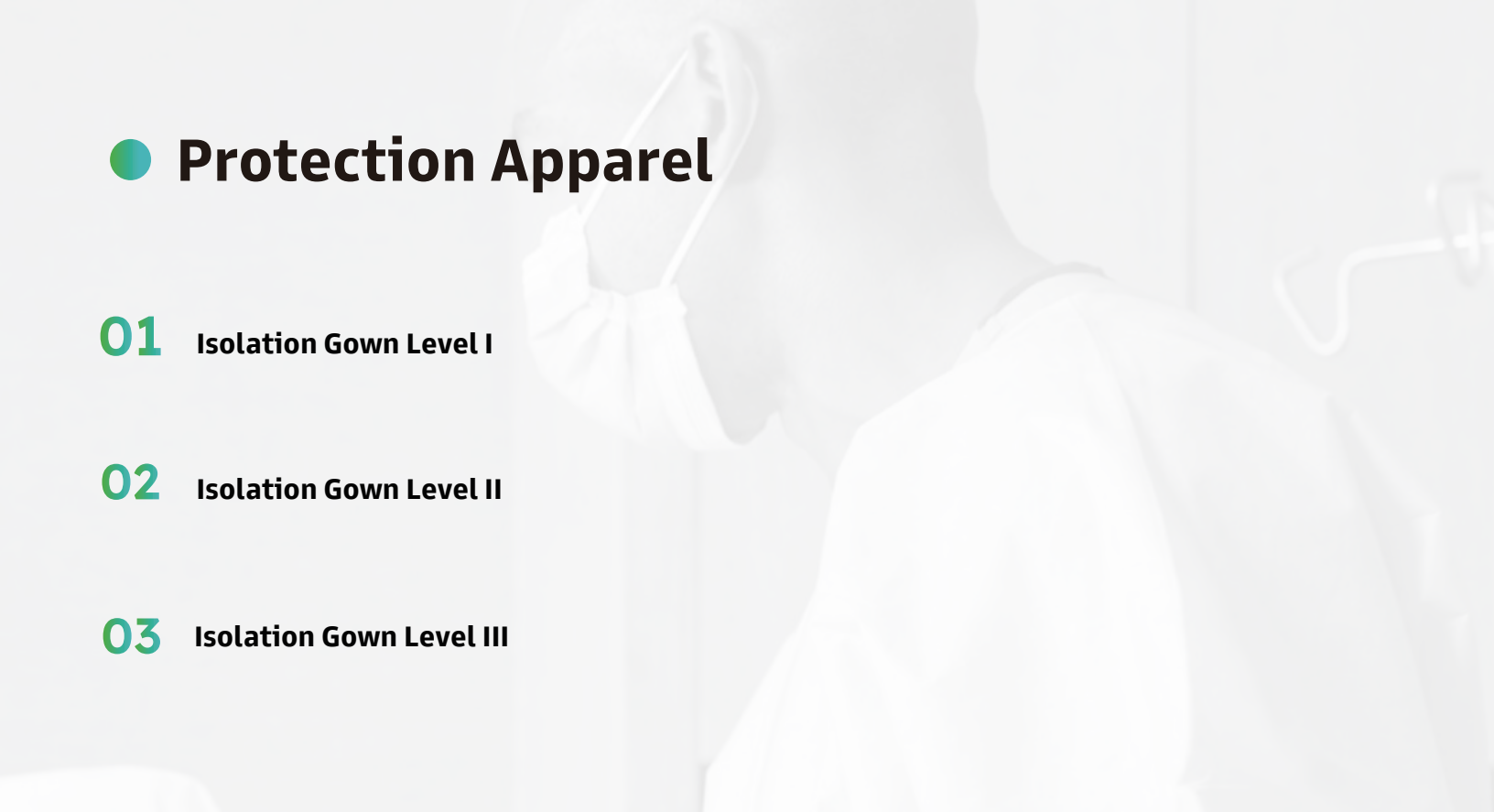


● Protection Apparel

01 Isolation Gown Level I

02 Isolation Gown Level II

03 Isolation Gown Level III



Isolation Gown

9934/9935/9937/9940

SIPA™ Heath Care AAMI Level I isolation gown is lightweight, multi-ply, made of soft, breathable PP+PE or SMS material for maximum comfort. It has elastic wrists and is available in universal and XL sizes.

- **AAMI Level 1** - BFE> 98%, non-woven fabric + meltblown protection layer + non-woven layer
- **Premium quality** - free from latex, ultra-low dermatitis risk and zero natural rubber latex allergy risk
- **Multi-Ply Design** - breathable material for good comfort
- **Lightweight construction** - for comfort and fit
- **Food contact approved** - safe for use with all food types
- **Color** - arctic blue (stock), yellow (upon request)

Technical Performance	
Classification	Single-use protective apparel, Class I Medical Device, Non-sterile, Latex-free
Approval	FDA Registration, CE Registration
Design	Tie Neck, Elastic Wrist (Customization Available)
Inspection Criteria	AQL 1.5
Shelf Life	3 years
Regulatory Compliance	<p>AAMI BP 70 Level I</p> <ul style="list-style-type: none"> - ANSI/AAMI PB70: 2012: Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities - Waterproof, bacterial-proof, virus-proof <p>Personal Protection Equipment Directive Approved</p> <ul style="list-style-type: none"> - 3D design - Material: PP+PE 33g, or SMS 35g - Size: Free size and XL, or as requested
Packaging	<p>Conform to CE standards</p> <ul style="list-style-type: none"> - Carton Dimensions: 57.5x37.5x37.5cm - 120 - Pcs/Carton - Gross weight 14 Kg
Applications	<p>General applications</p> <p>Community nursing, dental surgeries, emergency services, local authority, police, customs, food and catering, light industrial, general use</p>



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Infection Control Guide

Safety starts well before the moment a clinician enters the patient's room. Use the setting usage key and materials descriptions as a guide to select gowns and other apparel, so you can provide the right options for every situation.

Setting usage guidelines

The icons represented below should be used as a guideline in making gown selections for various needs and areas of your facility. Additionally, utilize the AAMI chart (see page 13) for the appropriate level gown.

 Standard Precautions	 Food Service	 Maintenance
 Contact Precautions	 Intensive Care	 Nursing
 Emergency	 Unit Lab	 Visitors

Per CDC Guidelines on Standard Precautions, the use of isolation gowns is indicated for some interactions between healthcare workers and patients. Transmission-Based Precautions (Contact, Droplet, and Airborne Precautions) are always used in addition to Standard Precautions. Isolation gowns are indicated for use whenever Contact Precautions are in effect and may be appropriate when Droplet and/or Airborne Precautions are in effect, depending on the nature of the interaction between the healthcare worker and patient as well as the extent of anticipated blood, body fluid, or pathogen exposure.

For more information, visit [cdc.gov](https://www.cdc.gov).

Source: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions:

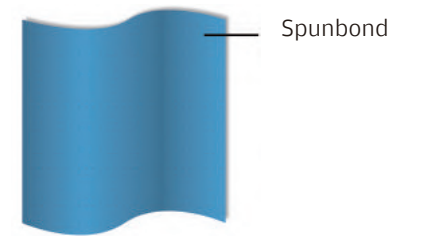
Preventing Transmission of Infectious Agents in Healthcare Settings

Materials Descriptions

Materials descriptions

Standard, cost-effective and comfortable

For basic infection control, this non-woven fabric bonds fibers together to form a single layer that is appropriate only for very minimal fluid exposure.

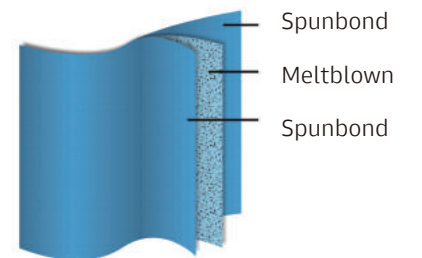


Spunbond

SMS Material

Balanced mix of protection and comfort

Strong and breathable, Spunbond/Meltblown/Spunbond (SMS) is a multi-layer fabric composed of inner layers of meltblown polypropylene between outer layers of spunbond polypropylene that is ideal for extended wear. Light/medium weight SMS is appropriate for low amounts of fluid and heavy weight SMS may be appropriate for moderate contact with fluids.



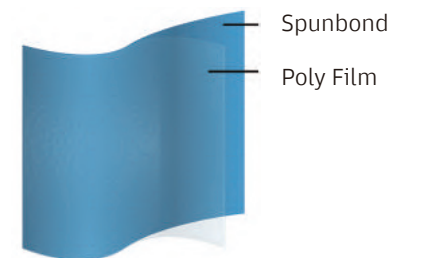
Spunbond

Meltblown

Spunbond

Coated Polypropylene ("Poly-coated")

Soft, spunbond polypropylene is coated with a layer of polyethylene (plastic) film.

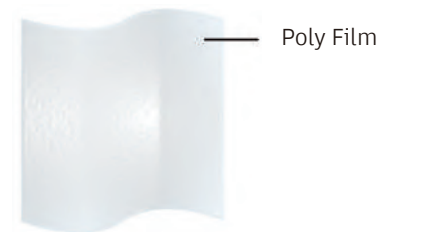


Spunbond

Poly Film

Polyethylene (Plastic) Film

A single layer of polyethylene (plastic) film provides protection at an affordable cost.



Poly Film

AAMI Level Guide

We're your source for AAMI compliant gowns. Choose the level you need, based on the green/orange/blue/purple color coding in the following chart.

AAMI PB70 Guidelines

ANSI/AAMI PB70 Barrier performance	Test method	Test definition	Requirement	Anticipated
AAMI Level 1	Water resistance: Impact penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	Water impact < 4.5 g	Minimal fluid levels
AAMI Level 2	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact	Spray impact < 1.0 g Hydrostatic Pressure > 20 cm	Low fluid levels
AAMI Level 3	Water resistance: Impact penetration AATCC 42 Water resistance: Hydrostatic pressure AATCC 27	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact	Spray impact < 1.0 g Hydrostatic pressure > 50 cm	Moderate fluid levels
AAMI Level 4	ASTM F1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System	ASTM F1671 Measures the resistance of materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact	Pass	High fluid levels

Many organizations have published general guidelines for the use of personal protective equipment, including gowns, within healthcare settings.

AAMI

Only the Association for the Advancement of Medical Instrumentation (AAMI) offers a widely accepted system of classification for protective apparel based on liquid barrier performance.

APIC Contact Precautions:

In addition to wearing a gown as outlined under Standard Precautions, wear a gown when entering the room if you anticipate that your clothing will have substantial contact with the patient, environmental surfaces, or items in the patient's room, or if the patient is incontinent or has diarrhea, an ileostomy, a colostomy, or wound drainage not contained by a dressing. Remove the gown before leaving the patient's environment. After gown removal, ensure that clothing does not contact potentially contaminated environmental surfaces to avoid transfer of microorganisms to other patients or environments.

APIC The Association for Professionals in Infection Control and Epidemiology (APIC) Standard Precautions:

Wear a gown to protect skin and to prevent soiling of clothing during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. Select a gown that is appropriate for the activity and amount of fluid likely to be encountered. Remove a soiled gown as promptly as possible, and wash hands to avoid transfer of microorganisms to other patients or environments or wound drainage not contained by a dressing. Remove the gown before leaving the patient's environment.

Style Guide

Key features like wrist, neck and back style can vary from gown to gown. Use this style guide to understand the differences.

Wrist Style Options

Elastic wrist



Hybrid elastic wrist and thumb hook



Thumb hook



Knit cuff

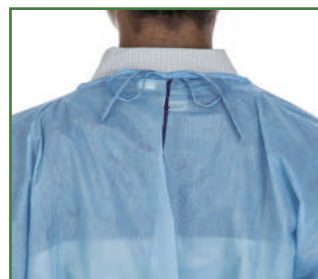


Neck Style Options

Tape tab



Tie-neck



Over-the-head



Hook and loop



Back Style Options

Open-back*



Full-back



Overlapping back panels and side ties (full-back)



● Covid-19 Testing Kits

01 PCR Sample Transport Kit

02 COVID-19 Antigen Rapid Test



PCR Sample Transport Kit

9955

SIPA™ Health Care Sample Transport Kit is designed to help everyone self-collect samples at the comfort and safety of their homes.

- **Easy and safe to use** - lab-developed and lab-tested sampling kits made for use at home
- **Premium quality** - high quality components assembled in an ISO-9001 certified sterile facility
- **No Guanidine** - friendly to most machines
- **Cost effective** - gets the job done at an affordable cost
- **No-hassle transportation** - do not need to be refrigerated
- **Transport medium color** - grapefruit red

Technical Performance	
Classification	Sampling Swab Kit, FMH - Specimen transpire and storage container
Approval	FDA Registration, CE Registration
Design	Kit - 4 Items
Inspection Criteria	AQL 1.5
Shelf Life	2 years
Regulatory Compliance	<p>Single Kit contains</p> <ul style="list-style-type: none"> - 10ml test vial with cap - 3ml transport medium (liquid) - Nasal swab, no break - Biohazard bag with absorbent pad <p>Transport Medium Components</p> <ul style="list-style-type: none"> - Tris(hydroxymethyl)aminomethane, 200mmol/L - Sodium Chloride, 400 mmol/L - Ethylene- Diamine-Tetra- Acetate (EDTA), 20mmol/L - Purified water, >99
Packaging	<p>Conform to FDA and CE standards</p> <ul style="list-style-type: none"> - Carton Dimensions: 57x50x42cm - 2000 Kits/Carton - Gross weight 14 Kg



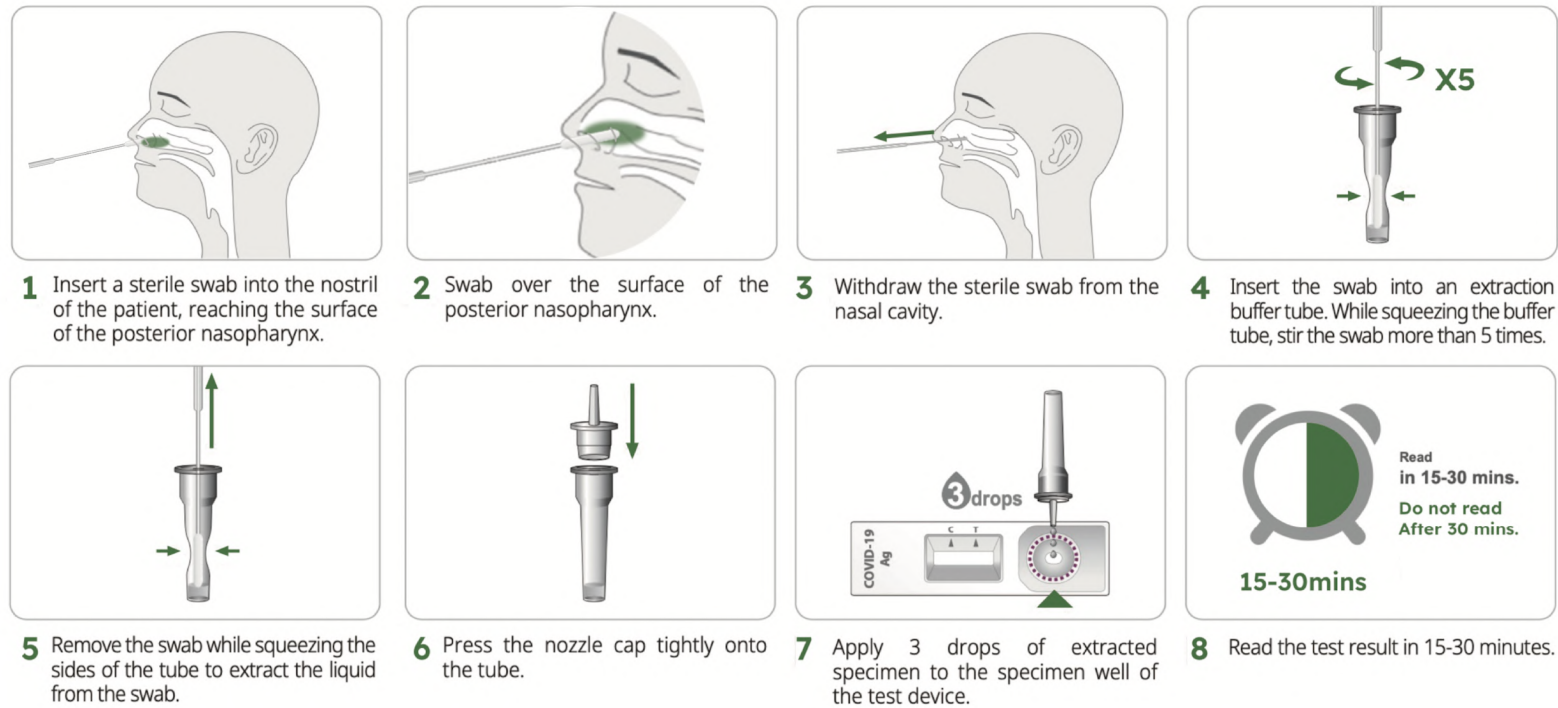
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 EMAIL contact@sipamed.com

COVID-19 Antigen Rapid Test

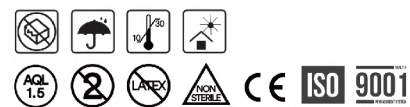
9954

SIPA™ Health Care SARS-CoV-2 Antigen Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

- **Easy and safe to use** - lab-developed and lab-tested sampling kits made for use at care centers and home
- **Premium quality** - high quality components assembled in an ISO9001 certified sterile facility
- **Cost effective** - gets the job done at an affordable cost
- **No-hassle transportation** - do not need to be refrigerated
- **Conforms to CE standards** - complied with ISO13485:2016
- **Global reception:** listed, distributed and used in EU and Asia



Spec	Test/Carton	Carton Size	Gross Weight
1 Test Packaging	360	405*595*320mm	10.0kg
5 Test Packaging	500	260*390*500mm	9.6kg
25 Test Packaging	500	260*390*410mm	8.0kg



25 Tests



25 Extraction Buffers



25 Swabs



User Instruction

*All Independently Packaged

Governance

At SipaMED, we adhere to sound corporate governance principles, ethics, and compliance in all aspects of our business. Our Board of Directors sets high standards for our directors, officers, employees, and for the conduct of our business worldwide. Our success is grounded in behavior that is based on demanding values. One such value is the belief in an uncompromised ethical standard.

We also maintain various compliance and training initiatives, including programs that address anti-bribery and anti-corruption, conflict minerals and supplier codes of conduct, third-party compliance and ethics, environmental compliance, trade compliance, and quality management systems.



Governance

DATA PRIVACY & CYBER SECURITY

We are committed to our customer's privacy. We know that we must earn trust and keep it every time our customers use our products and services to transform the way the world works.

Our Office of Data Protection and Office of Data Governance work together with the goal of ensuring that personal data is collected, shared, and handled appropriately. We start with a commitment to:

- Being transparent in how and when we collect and use personal data. Simplifying our policies so they are easy to understand
- Reinforcing best practices and standardizing processes in managing customer data assets. Acting as good stewards of customer data we receive and process

Our approach to security includes focused efforts on everything from product development to managing and monitoring our infrastructure and our environments. We utilize industry standards where possible to ensure consistency and best practices across the organization.

As a customer-focused organization, security is embedded and operationalized continuously throughout the development lifecycle and aligned to an enterprise framework that ensures all products have consistent security levels. This allows us to monitor and address any potential issues with our products before customers begin using them in the field.

Equally important, we monitor the infrastructure and the environments in which our solutions are deployed. Many different approaches and techniques are used including managing identity and access, vulnerability management, and intrusion detection solutions on networks and systems. All of these approaches work together, with appropriate incident response, to maintain a high level of security for our customer solutions.

RISK MANAGEMENT

At SipaMED, risk management is a critical element in promoting the sustainability, resilience, and value of the company. We focus on four main risk categories:

1. Hazard
2. Operational
3. Financial
4. Strategic

We believe that risk is best mitigated when all our business divisions are involved. Business division leaders act as company-wide risk champions by raising awareness, sharing leading practices, and facilitating compliance and other risk management activities. Together, along with our Enterprise Risk Management leader, divisional leaders present the top inherent risks that could pose a material threat to established risk tolerances as well as stockholder value. This information, along with a summary of key risk management activities, is presented annually to our Board of Directors.

We manage risks in the following ways:

- The Audit Committee of the Board of Directors and the management of the company are responsible for risk management.
- We have an Enterprise Risk Management (ERM) process that is led by an ERM leader.
- Regular, on-going management and review processes allow us to actively manage both strategic and operational risks with a forward-looking view.
- Surveys and interviews are conducted on an annual basis and are aimed at identifying and ranking the top 10 inherent compliance and hazard risks.
- Risk owners exist at every level of the organization.
- We conduct compliance and hazard risk assessments to identify, assess, and treat risks while establishing risk tolerances and prioritizing resources.

Governance

SUPPLIER CODE OF CONDUCT

We seek to establish relationships exclusively with third-party partners who share our commitment to conducting business fairly, legally, ethically, and transparently. As a global company:

- We implement and monitor policies that ensure all operations — including all suppliers, vendors, and contract manufacturers — fully comply with local and national laws wherever we conduct business.
- We set standards for our company, suppliers, and partners through our Our Supplier Code of Conduct, Business Ethics and Conduct Policy, and Conflict Minerals Policy.
- We prevent modern slavery, human trafficking, anti-bribery misconduct, and conflict mineral sourcing in our supply chain. Trimble may request that new and existing suppliers perform assessments and/or audits in compliance with our Code of Conduct requirements.

BOARD OF DIRECTORS COMPOSITION & DEI

Our Board of Directors recognizes that our success over the long term requires a strong corporate governance framework. Below are highlights of our corporate governance framework:

- Our directors are elected annually.
- We separate the positions of Executive Chairman of the Board, CEO, and Lead Independent Director, which provides a balance in our leadership structure and helps ensure a strong, independent, and active Board.
- In uncontested elections, our directors must be elected by a majority of the votes cast and an incumbent director who fails to receive a majority is required to tender their resignation.
- We have no super majority voting requirements in our Certificate of Incorporation or Bylaws.
- We focus on board refreshment and diversity, as evidenced by the fact that nearly half of our directors have less than five years of tenure and four out of eleven of our directors are female or diverse.
- A succession planning process is in place, and we actively plan for executive succession on ongoing basis.

HUMAN RIGHTS IN SUPPLY CHAIN

Respect for human rights is a fundamental value of SipaMED. We promote and protect human rights and believe it is our duty to cultivate ethical labor practices wherever we do business. Additionally:

- We condemn all forms of exploitative working conditions including all forms of forced labor and exploitative child labor.
- We are committed to eradicating the risk of slavery and human trafficking in our supply chain.
- Our Partner Code of Conduct requires that SipaMED's suppliers and partners operate with the highest ethical standards and support the fundamental human rights outlined by SipaMED.

We promote and protect human rights and believe it is our duty to cultivate ethical labor practices wherever we do business.

ANTI-CORRUPTION / ANTI-BRIBERY

All directors, officers, employees, agents, consultants, and representatives of SipaMED throughout the world are expected to be aware of and abide by the requirements of anti-corruption laws. We have implemented policies against corruption and unethical business behavior and abides by international efforts supporting anti-corruption laws including:

- The Foreign Corrupt Practices Act (FCPA) and the laws of many countries that specifically prohibit corrupt payments to public officials.
- Our Business Ethics and Compliance Policy and applicable anti-corruption laws such as the UK Bribery Act also prohibit corrupt payments for any purpose, including corrupt payments involving only private parties.

Appendix

Certifications

Category	Certification
General	FDA Registration
	FDA 510(K)
	CE
	CE Module C2
	ASTM D6978-05 Chemo-Rated
	ASTM D6319
	ASTM F1671
	ISO 10993
	CE TYPE-C Chemical-K (EU)2016/425 PPE & 89/686 EEC
EN 374-2: 2014	
EN 374-4: 2013	
EN 374-5: 2016	
EN 420: 2003 + A1: 2009	
ISO 3071: 2016	
ISO/TS 16186: 2012 & ISO/TS 161890: 2013	
CE TYPE-B Chemical-KPT (EU)2016/425 PPE & 89/686 EEC	EN 374-1: 2016
	EN 374-2: 2014
	EN 374-4: 2013
	EN 374-5: 2016
Additional	EN 455-1: 2000
	EN 455-2: 2015
	EN 455-3: 2015
	EN 455-4: 2009
Supplements	Food Contact: EU CE
	SVHCs Standards

Category	Certification
Factory Standards	ISO 9001: 2015
	ISO 13485: 2016
	YY/T 0287-2017
	GB/T 19001-2016
	GB 10213-2016
	GB 4806.11-2016
Industrial	EN 388: 2016 - 4121
Sipa Plant	World Emergency Rescue Organization Authorization
	Declaration of Conformity
	Certificate for Exportation of Medical Products
	Medical Equipment Production Certificate





by

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