

# NEXERA

M E D I C A L



**SPECTRA SHIELD™**  
*The next generation of respiratory protection*



**THE FIRST GLOBAL LINE OF ANTIMICROBIAL RESPIRATOR MASKS**



GUARDIAN (Valve)



DEFENDER



PROFESSIONAL



PROTECTOR (Child)



GUARDIAN

- N95, N99, FFP2, and FFP3
- **Reusable** up to 14 days\*\*
- Single Use for **extended wear up to 12 hours\***
- Molded and flat-fold designs
- Adult (large) and children's (small) sizes\*\*\*
- Cleared by the **FDA and E.U. (CE Mark)**
- Superior respiratory protection
- **Self-sanitizing** for added protection
- Universal Fit for all facial shapes and sizes
- Safe, natural & non toxic
- PVC Free, Latex Free, Non-allergenic

\* N95 for United States, N99 for Canada, FFP 2 & 3 for European Union  
 \*\* For European Union & Canada only \*\*\* Not for sale in the United States



**PRODUCT  
SPECS**

**Antimicrobial Respirator Masks**  
(E.U. Approved with CE Mark)

**Antibacterial**  
(FDA Approved)



| Model                  | Guardian FFP3 RD   | Defender N99                      | Protector (Child) N99             | Guardian FFP2 RD   | Professional N95                                      |
|------------------------|--|-----------------------------------|-----------------------------------|--|---|
| Style                  | Flat-Fold with Valve   | Molded                            | Molded                            | Flat Fold No Valve   | Molded  |
| Region                 | International  | International                     | International                     | International  | United States   |
| Reusable up to 14 days | YES (E.U.)   | YES (Canada)                      | YES (Canada)                      | YES (E.U.)   | NO  |
| Effective Against      | Viruses, Mold, Bacteria, Fungus                              | Viruses, Mold, Bacteria, Fungus   | Viruses, Mold, Bacteria, Fungus   | Viruses, Mold, Bacteria, Fungus                              | Bacteria  |
| Certifications         | FFP3 RD<br>CE EN 14683 Type IIR<br>CE EN 149:2001 & A1: 2009 | Canadian Type 1<br>Medical Device | Canadian Type 1<br>Medical Device | FFP3 RD<br>CE EN 14683 Type IIR<br>CE EN 149:2001 & A1: 2009 | FDA Class II<br>Medical Device<br>NIOSH 42CFR Part 84 |

# BE PROTECTED



A powerful sneeze can produce nearly 40,000 aerosol droplets which are propelled through the air at great force. The most common estimates for the speed these droplets travel is around **95 mph**, but some people may be able to reach **650 mph** for their sneezes. This is the main reason that airborne diseases can be so easily spread throughout the population.

# THIS IS HOW IT PROTECTS

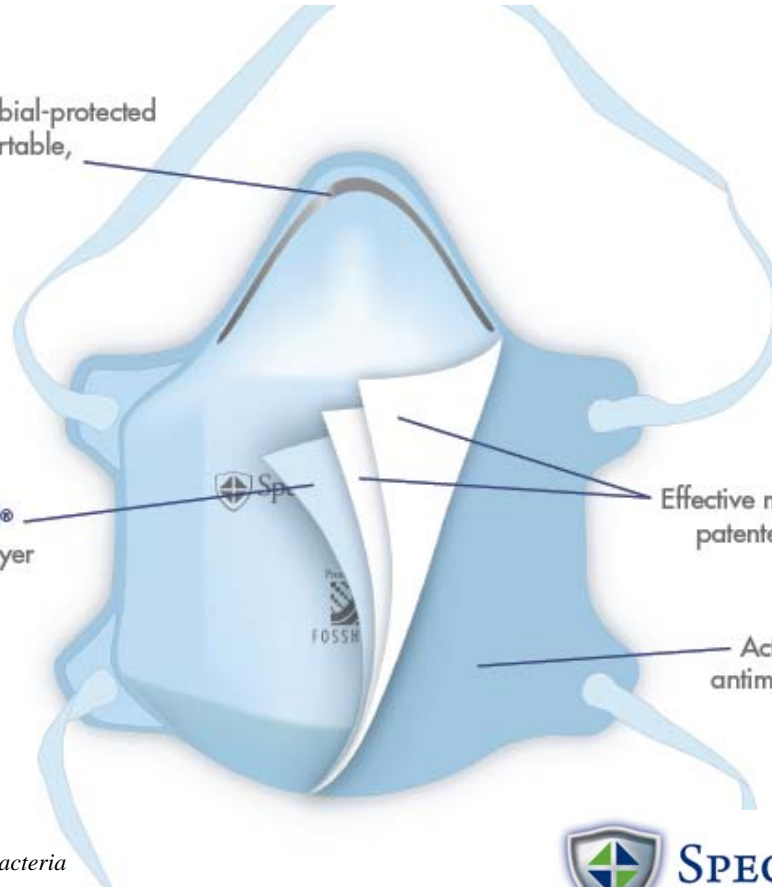
The SpectraShield™ Mask, captures microbes, then inactivates or kills them\*

Flexible outer metal and antimicrobial-protected inner nosepieces – create a comfortable, snug fit with no air leakage

Active microbe-killing **Fosshield®** antimicrobial-protected outer layer

Effective microbe-capturing patented filtration layers

Active microbe-killing **Fosshield®** antimicrobial-protected inner layer



\*Antimicrobial performance inactivates viruses and kills bacteria

The SpectraShield™ Mask filters over 3,500% better than an ASTM F2100-07 high barrier mask



Gaps Around Nose Causes Air Leakage

No Snug Fit – Loose Ear Straps Causes Air Leakage

No Filtration Capability

Snug Fit  
Dual Elastic Straps  
No Air Leakage



Tight Fit Around Nose No Air Leakage

Superior Filtration  
Filters out up to 99% of particulates

ASTM F2100-07 High Barrier Surgical Mask

SpectraShield™ Antibacterial N95, Antimicrobial N99, FFP2 & FFP3 Respirators

## COMPETITIVE REVIEW

The SpectraShield™ mask is superior to other antimicrobial and antibacterial masks available in the market.

|   | Nexera Spectra Shield | Kimberly Clark All Masks | 3M All Masks | Filigent BioMask | GSK ActiProtect |
|---|-----------------------|--------------------------|--------------|------------------|-----------------|
| NIOSH Cleared as a Respirator   | YES                   | YES                      | YES          | NO               | NO              |
| Long Lasting – Continuous Kill Antimicrobial Agent                                    | YES                   | NO                       | NO           | NO               | NO              |
| Approved for Extended Wear up to 12 Hours in the US by the FDA                        | YES                   | NO                       | NO           | NO               | NO              |
| REUSABLE Certified by EU with a CE Mark   | YES                   | NO                       | NO           | NO               | NO              |
| Use of Silver & Copper, known natural effective nontoxic antimicrobials for centuries | YES                   | NO                       | NO           | NO               | NO              |
| Multiple Respirator Mask Designs including Molded and Flat Fold, valve and non-valve  | YES                   | YES                      | YES          | NO               | NO              |

# The SpectraShield™ Series of Antimicrobial Masks offer:



**SUPERIOR RESPIRATORY PROTECTION**

**PROTECTION DURING A HEALTH CRISIS**

**REDUCED CROSS CONTAMINATION**

**EASY BREATHING AND COMFORT**



**KILLS TUBERCULOSIS, MRSA, BIRD FLU, SWINE FLU AND MORE**

*\* Antimicrobial Masks are NOT available in the United States. Only Antibacterial Masks are available in the United States .*

# The SpectraShield™ Mask is Safe and Effective

- ❖ The SpectraShield™ Mask is:
  - ❖ Non-toxic
  - ❖ Latex-Free, PVC-Free, and non-allergenic
  - ❖ Non-irritating
- ❖ Safe and secure anti-microbial agent that does not gas off or leach off to be inhaled or ingested.
- ❖ All test results were compiled in a Safety Summary Analysis which indicated the SpectraShield™ Mask to be deemed safe and effective by the FDA.

## BIOCOMPATIBILITY

| Test                    | Outcome                            |
|-------------------------|------------------------------------|
| Dermal Sensitivity      | Scored "0" on test -No sensitivity |
| Primary Skin Irritation | Scored "0" on test –No irritation  |
| Systemic Toxicity       | Test showed "No toxicity"          |
| Gas-Off/Leach-Off       | No measureable amounts             |
| Cytotoxicity            | Not toxic to human cells           |
| Fluid Resistant         | Highly fluid resistant             |

All Biocompatibility Tests were performed in FDA Certified Independent Laboratories

## FDA DEEMED "SAFE AND EFFECTIVE"

### Revolutionary New FDA-Cleared SpectraShield™ N95 Antibacterial Surgical Respirator Mask

#### First to Use Antimicrobial Textile

- Simultaneous clearance by FDA & NIOSH.
- Tested and proven for extended wear up to 12 hours.
- The technology eliminated "breathing zone" concerns of the FDA.
- Patented technology – proven performance.
- Meets CDC & WHO guidelines for infections disease exposure control.
- Effective against certain bio-terrorism illnesses such as Tuberculosis.

SpectraShield™  
receives clearance for  
a new class of  
Antimicrobial Medical  
Devices called "ONT"



**SPECTRA SHIELD™**  
The next generation of respiratory protection

## E.U. DEEMED "REUSABLE"

### Revolutionary New European Union Cleared SpectraShield™ FFP2 RD and FFP3 RD Antimicrobial Respirator Mask

#### First to Use Antimicrobial Textile

- The FIRST AND ONLY antimicrobial reusable FFP2 & FFP3 respirator masks.
- Tested and proven for reuse for up to 14 days.
- Patented technology – proven performance.
- Meets CDC & WHO guidelines for infections disease exposure control.
- Effective against certain bio-terrorism illnesses such as Tuberculosis.



**FFP2 RD**

FFP3 (WITH VALVE  
IS ALSO AVAILABLE)

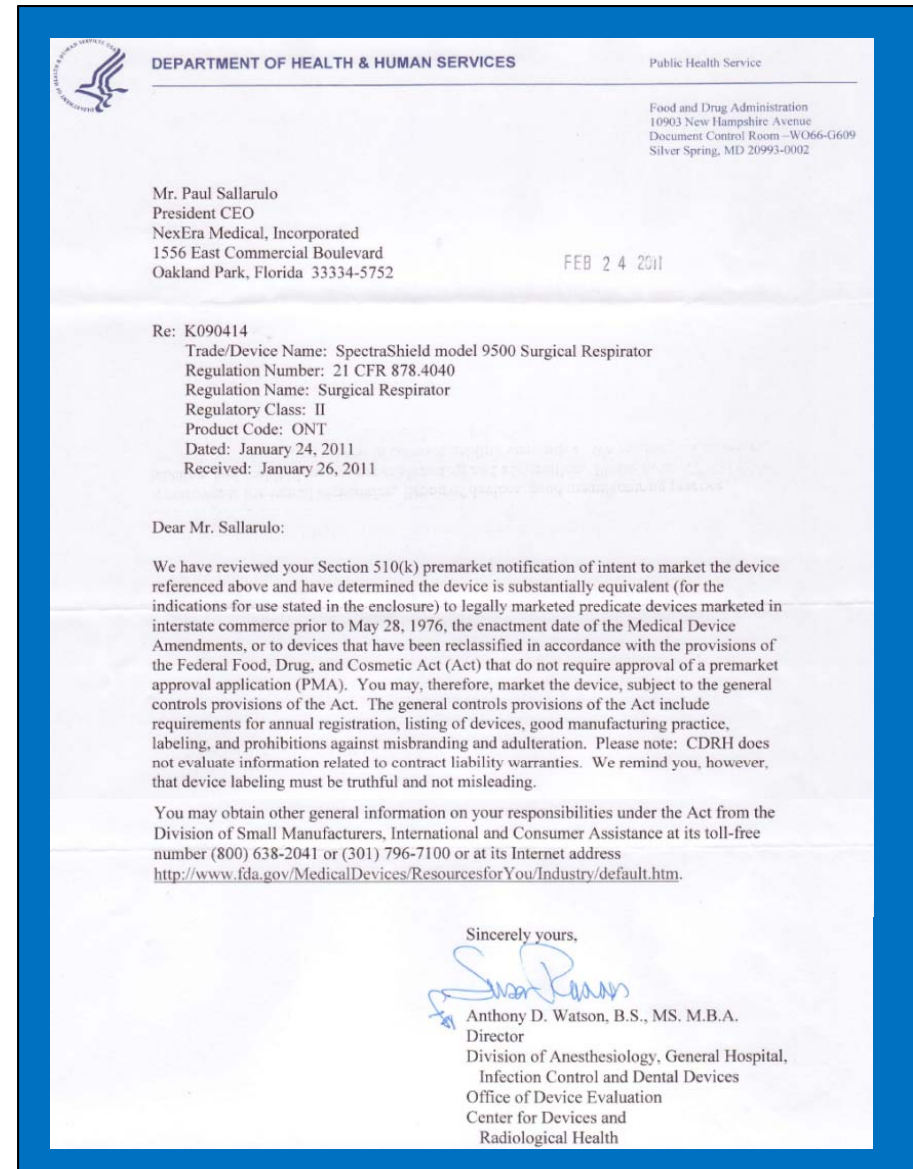


**SPECTRA SHIELD™**  
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# The SpectraShield™ Mask is FDA Cleared

With Long-Lasting and Continuous Kill Performance, the SpectraShield Mask:

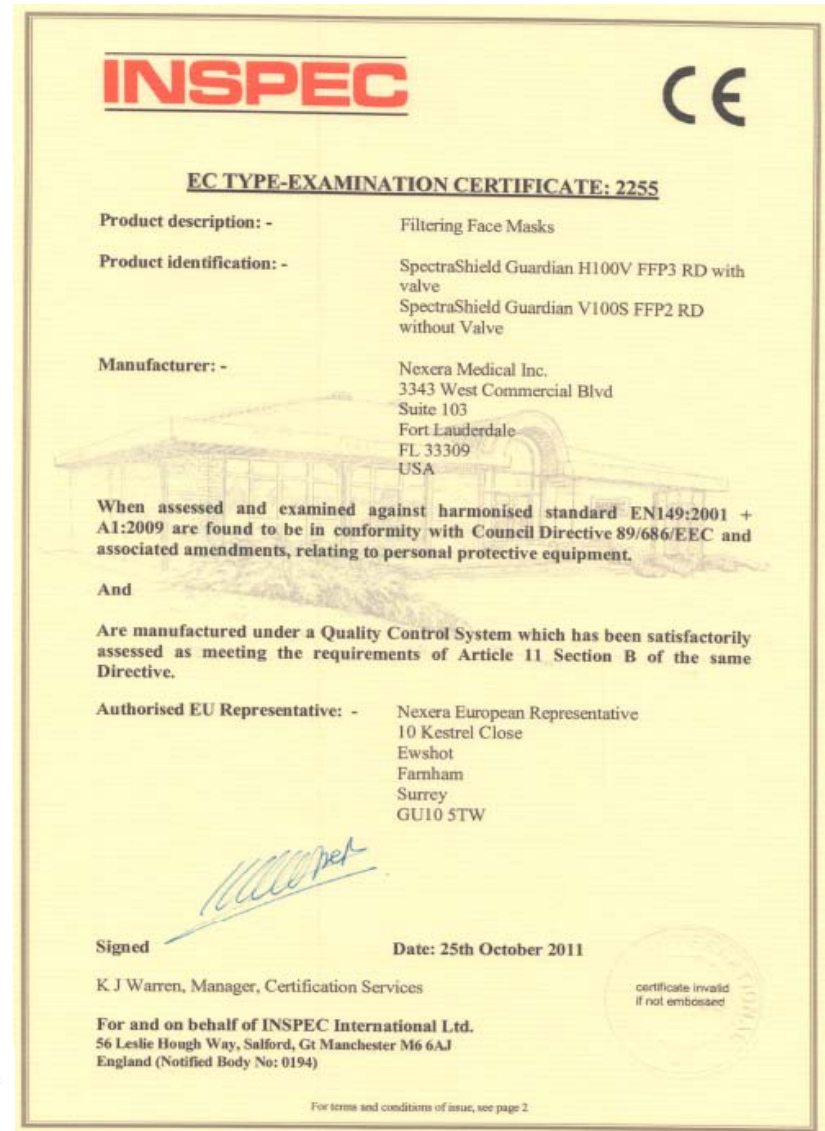
- Cleared as an N95 Antibacterial Surgical Respirator
- Meets requirements for surgical respirator as a Class II Medical Device
- Tested and proven for "Extended Wear" with performance up to 12 hours when exposed to sweat and saliva
- Passed all safety related testing including, toxicity, biocompatibility, gas-off / leach-off, fluid resistance, and dermal sensitivity



# The SpectraShield™ Mask is CE Certified as a REUSABLE ANTIMICROBIAL FFP2 RD & FFP3 RD MASK CE EN149:2001 & A1:2009

With Long-lasting and Continuous Kill performance, the SpectraShield™ Mask:

- CE Cleared as a REUSABLE Antimicrobial Respirator Mask
- CE Cleared FFP2 RD (no valve) and FFP3 RD (with valve) EN 14683 Type IIR
- Tested and proven for "Extended Wear" with performance up to 12 hours when exposed to sweat and saliva
- Complies with 2008 European Communities Medical Device Directive 93/42/EEC
- All tests conducted at ISO Certified independent testing facilities in the European Union



*FFP 2 & FFP3 Reusable Antimicrobial Masks are NOT available in the United States.*

# The SpectraShield™ Mask is Canadian Cleared as a N99 Reusable Antimicrobial Respirator

With Long-lasting and Continuous Kill performance, the SpectraShield™ Mask:

- Cleared as an N99 Reusable Antimicrobial Respirator
- Reusable up to 14 days
- Meets requirements for respirator mask as a Class I Medical Device
- Tested and proven for "Extended Wear" with performance up to 12 hours when exposed to sweat and saliva
- Passed all safety related testing including, toxicity, biocompatibility, gas-off / leach-off, fluid resistance, and dermal sensitivity



*N99 Reusable Antimicrobial Masks are NOT available in the United States.*

|   |   |   |  |
|---|---|---|--|
| Health Canada / Santé Canada  |   | Health Products and Food Branch Inspectorate / Inspecteurat de la Direction générale des produits de santé et des aliments  |  |
| Licence Number / Numéro de la licence: <b>2830</b>  |   |   |  |
| <b>Medical Device Establishment Licence</b>   |   | <b>Licence d'établissement pour les instruments médicaux</b>  |  |
| <b>NEXERA MEDICAL</b><br>1556 EAST COMMERCIAL BLVD<br>FORT LAUDERDALE, FLORIDA<br>UNITED STATES<br>33334  |   |   |  |
| This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:   |   | Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:  |  |
|   | Distributor / Distributeur  | Importer / Importateur  | Manufacture Devices for Retail Sale / Fabricant d'instruments médicaux de classe 1 |
| Class I / Classe I  | No / Non  | No / Non  | Yes / Oui  |
| Class II / Classe II  | No / Non  | No / Non  |  |
| Class III / Classe III  | No / Non  | No / Non  |  |
| Class IV / Classe IV  | No / Non  | No / Non  |  |
| Attestation made :  |   | Attestations faites :   |  |
| The establishment has documented procedures in place in respect of: <ul style="list-style-type: none"> <li>• distribution records</li> <li>• complaint handling</li> <li>• recalls</li> <li>• mandatory problem reporting</li> <li>• handling, storage, delivery</li> <li>• installation</li> <li>• corrective action</li> <li>• servicing</li> </ul> |   | L'établissement a mis en oeuvre une procédure écrite concernant: <ul style="list-style-type: none"> <li>• les registres de distribution</li> <li>• les plaintes</li> <li>• les rappels</li> <li>• rapports d'incident obligatoires</li> <li>• la manutention, le stockage, la livraison</li> <li>• l'installation,</li> <li>• les mesures correctives</li> <li>• l'entretien</li> </ul> |  |
| Site listing begins on the back of this page<br>Expiration Date: 2011-12-31   |   | Liste des sites commence au verso de cette page   |  |
| Minister of Health / Ministre de la santé<br>Basanti Ghosh  | Countersigned: Director General, Health Products & Food Branch Inspectorate or delegated authority / Contresigné par: Directeur Général, inspecteurat de la Direction générale des produits de santé et des aliments ou autorité déléguée<br>Director Compliance Coordination & Licensing Division<br>FEB 17 2011 |   |  |
| <small>This licence is the property of the Health Products &amp; Food Branch Inspectorate and must be returned upon demand. / Cette licence appartient au programme d'inspecteurat de la Direction générale des produits de santé et des aliments et doit être retournée sur demande.</small>   |   |   |  |
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