"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm"

Florence Nightingale
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Bude Medical

ISO 9001:2000
ISO 13485:2003

Arjowiggins

Sterilization Paper

ISO 9001:2000
ISO 14001:2004
EN 868-2

Quimica Del Santo
(Steam Indicators and Bowie Dick Test Pack)

ISO 9001:2000
ISO 11140-1
EN 867-1

Indicators

Class 4 (ISO 11140-1) and Class D (UNE-EN 867-1)

Integrator and

Bowie-Dick Test Pack

Class D (UNE-EN 867-1) Class 2 (ISO 11140-1) and Class B (UNE-EN 867-1)
Microbiology is the study of **microorganisms**, which are **unicellular microscopic organisms**.

Bacteria and viruses form part of microbiology.

Some bacteria serve to protect the body, these are “good bacteria”/normal flora. By living in the human body they prevent infection by the “bad bacteria” and viruses and aid in certain bodily functions like digestion. The “good bacteria” have a mutualistic relationship with its host, as the host helps with the survival of the bacteria and the bacteria protects the host. The “good bacteria” can cause infection when the host’s immune system is compromised.
Some bacteria and all viruses responsible for diseases in the human body need a host (human body) to enable them to function and multiply – these are parasitic or pathogenic microorganisms. Pathogenic bacteria cause typhoid fever; diphtheria; syphilis; cholera; food-borne illness and tuberculosis. In many viral infections the viruses do not kill the cell or have any immediate impact on its function. The DNA of these viruses often lies quietly in the nucleus of cells for years without producing more virus particles. This type of infection is referred to as a latent viral infection. Several viruses appear to establish an infection in which the virus continually produces viral particles but the immune system is unable to fight the disease. This type of infection is referred to as a persistent viral infection. The common cold; rabies and HIV are all caused by viral infections.

Pathogens require optimal conditions for their growth and multiplication i.e. temperature, moisture etc. Most pathogens that infect the human body function at $37^0$C, which is why a fever occurs when you are sick as the body raises its temperature to try and kill the pathogens.

Bacterial infections may be treated with antibiotics however increased use of antibiotics contributes to the rapid development of antibiotic resistant bacteria. Antibiotic resistant bacteria is difficult to treat and therefore very difficult to eradicate.

Infections can be prevented by aseptic measures such as sterilizing the operating field and by proper care of indwelling catheters. Surgical and dental instruments are also sterilized to prevent contamination and infection by bacteria. Disinfectants are used to kill bacteria or other pathogens on surfaces to prevent contamination and further reduce the risk of infection.

We will now explore a BACTERIAL BARRIER for HUMAN PROTECTION.
Medical Paper Range
Key Characteristics

- Ability to allow the sterilizing agent to penetrate
- To provide a microbial barrier
- Maintains sterility of the wrapped surgical instrument
- Drapeability
- Puncture resistance
- Resistance to tearing
- Liquid resistance
- Non-linting
- Non-toxic
- No odour
- Biodegradable
- Low in cost

Governed by standards
ISO11607 & EN 868
4 Applications for Medical Paper

1) Sterilization Wraps
   - basins
   - instrument packs
   - gowns

2) Container Filter – Sterilization Containers
   - Expensive
   - Storage Space needed
   - Cleaning costs
   - Heavy
   - Hot after sterilization
   - No flexibility-fixed sizes
   - Not reliable- never know when to change container

3) Tray Liner – Material can absorb 4x its own weight

4) Drapes and Table Covers
Grading of Paper

- **Crepe**
  - Strength: -
  - Drapeability: -
  - Fluid resistance: -

- **Reinforced crepe**
  - Strength: +
  - Drapeability: -
  - Fluid resistance: -

- **Non woven**
  - Strength: +
  - Drapeability: +
  - Fluid resistance: +
Different Generations of Paper

Crepe

New Linen

Ré-processed Linen

Reinforced crépe

Non woven

G1

G3
The first generation is the original material offering the best bacterial barrier and the most cost effective and environmentally friendly wrap.

The composition of the Generation 1 paper consists >95% of cellulose (wood pulp) + some additives to give it some water repellancy.

- Steri 22 (standard crepe), 60gsm
- Steri 25 (soft crepe), 60gsm

It can be used as central sterilisation wrap, particularly for small and medium sized packs and trays. Table covers and trolley covers.

Sterilisable by steam, EO and FO
The second generation provides an affordable balance of drapeability and softness with the barrier performance and strength.

The composition of Generation 2 paper >80% cellulose and is reinforced with synthetic binders (<20%) to increase its durability and water repellancy.

• Steri 44 blue, 60gsm
• Steri 66 green, 70gsm
• Steri 175 - alcohol repellent (generation 2+)

It can be used as central sterilisation wrap, particularly for medium and large size trays and mid-weight packs. Table covers, trolley covers and container inner wrap.
The third generation, with its unique formulation, offers a superb combination of fluid repellancy (to both water and alcohol), drapeability, softness and strength for the most demanding applications.

Generation 3 paper consists cellulose (>50%) and synthetic fibre blend with synthetic binders (<50%)

- Steri 77+, 57gsm
- Steri 100, 60gsm
- Steri 88, 78gsm

It can be used as central sterilisation wrap for theatre trays, particularly for large trays and heavy duty packs. Orthopaedic trays and packs. Operating room sterile fields, table and trolley covers and container inner wrap.

Sterilised in latest steam, EO and EO gas
## Paper vs. Linen

<table>
<thead>
<tr>
<th><strong>PAPER</strong></th>
<th><strong>LINEN</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 85-95% BFE depending on generation of the paper.</td>
<td>• 48% BFE <em>(Bacterial Filtration Efficacy)</em></td>
</tr>
<tr>
<td>• 30 days shelf life with 0% infection.</td>
<td>• 33.5% infection if kept on shelf for 30 days</td>
</tr>
<tr>
<td>• Disposable</td>
<td>• Re-usable</td>
</tr>
<tr>
<td>- Decreased Nosocomial infections</td>
<td>- Fibres break down through repetitive laundering and use</td>
</tr>
<tr>
<td>- Environmentally friendly</td>
<td>- 1) weak spots + pinholes, therefore decreasing BFE</td>
</tr>
<tr>
<td></td>
<td>2) cleaning costs</td>
</tr>
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</table>

*Nosocomial infection = Any infection that is not present or incubating at the time the patient is admitted to the hospital*
Linen

Fibres uniformly woven give good strength, but the holes that can be seen allow for bacteria to get in to the pack.

Paper

The dense network of cellulose fibres creates an effective barrier to micro-organisms.
The combination of dense and matted blend of cellulose & synthetic fibres reinforced with synthetic binders provide increased strength, softness & drapeability whilst maintaining an excellent barrier to micro-organisms.
Fluid droplet in contact with Linen and with Paper.

Due to the natural absorbancy of Linen, the droplet passes straight through.

With the repellent qualities of Paper the passage is inhibited.
Utilisation of the product at the hospital
1. Place items assembled for pack in center of two sheets of wrapping material.

2. Fan-fold open end away from you over items. Cuff top layer.

3. Repeat same procedure with end toward you, lining up cuff directly on top of first cuff.

4. Miter left end and fold neatly up and over top of pack.

5. Repeat with right side of pack.

6. Repeat step 2.

7. Repeat step 3.

8. Repeat step 4.

9. Repeat step 5 and securely affix with pressure-sensitive indicator tape over end.

**FIG. 18-1** Square fold for wrapping item for sterilization. Single-layer (double-thickness) heavy wrap may be applied in a nonsequential manner. (Modified from the Association for the Advancement of Medical Instrumentation: Good hospital practice: steam sterilization and sterility assurance, ANSI/AAMI ST46-1993, Arlington, Va, 1993, American National Standards Institute.)
## EN 868-2 requirements

<table>
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<tr>
<th>Characteristics</th>
<th>Methods</th>
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<th>G3</th>
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<td>/</td>
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<tr>
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<td>2 mini</td>
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<td>Pore diameter</td>
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<td>/</td>
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<td>/</td>
<td>s</td>
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<td>-</td>
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<td>5 spots 1mm diam maxi / 100 cm²</td>
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## TECHNICAL DATA SHEET

**Customer:** SAMD  
**Product:** Non Woven Green  
**Product Code:** 0131000  
**Revision:** 02  
**Date:** 12/02/2004

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Non Woven Green is made according to EN ISO 9001
# TECHNICAL DATA SHEET

**Customer:** SAMD  
**Product:** Soft Crepe Blue

**Revision:** 04  
**Date:** 19/06/2007

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Soft Crepe Blue (Product Code : 0075000) is made according to EN ISO 9001

This document replaces all preceding Technical Data Sheets  
Expiry date, 07-2008
# TECHNICAL DATA SHEET

**Customer:** SAMD  
**Product:** S22 Green  
**Revision:** 06  
**Date:** 18/06/2007

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<td>ISO 1924-2</td>
<td>2.1</td>
</tr>
<tr>
<td>TENSILE STRENGTH CD</td>
<td>kN/m</td>
<td>ISO 1924-2</td>
<td>1.8</td>
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<tr>
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<td>kN/m</td>
<td>ISO 3781</td>
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</tr>
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<td>kN/m</td>
<td>ISO 3781</td>
<td>0.5</td>
</tr>
<tr>
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<td>%</td>
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<td>11</td>
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<tr>
<td>STRETCH CD</td>
<td>%</td>
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<td>5</td>
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<td>mN</td>
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<td>800</td>
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<tr>
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<td>mN</td>
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<tr>
<td>BURST STRENGTH</td>
<td>kPa</td>
<td>ISO 2758</td>
<td>190</td>
</tr>
<tr>
<td>WATER REPELLENCY</td>
<td>s</td>
<td>ASTM D779-03</td>
<td>25</td>
</tr>
<tr>
<td>DRAPE MD</td>
<td>mm</td>
<td>EN 868-2 (app.D)</td>
<td>110</td>
</tr>
<tr>
<td>DRAPE CD</td>
<td>mm</td>
<td>EN 868-2 (app.D)</td>
<td>135</td>
</tr>
<tr>
<td>PORE SIZE</td>
<td>μm</td>
<td>EN 868-2 Annex C</td>
<td>25</td>
</tr>
<tr>
<td>THICKNESS CREPE PAPER</td>
<td>μm</td>
<td>ISO 12625-3</td>
<td>175</td>
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<tr>
<td>FLUORESCENCE</td>
<td>%</td>
<td>DIN 58953-6</td>
<td>Nil</td>
</tr>
<tr>
<td>pH OF AQUEOUS EXTRACT</td>
<td></td>
<td>ISO 6588-2</td>
<td>7</td>
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<tr>
<td>SULFATE CONTENT</td>
<td>%</td>
<td>ISO 9198</td>
<td>0.018</td>
</tr>
<tr>
<td>CHLORIDE CONTENT</td>
<td>%</td>
<td>ISO 9197</td>
<td>0.015</td>
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<tr>
<td>RESISTIVITY</td>
<td>ohm</td>
<td>BS 6524</td>
<td>1.6×10⁴</td>
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</table>

S22 Green (Product Code : 0067000) is made according to EN ISO 9001

This document replaces all preceding Technical Data Sheets  
Expiry date, 07-2008
ARJOWIGGINS

TECHNICAL INFORMATION NOTICE
TO SAMD

Address: N°3 Drakensberg Drive
Longmedow West Business Park
Longmedow
ENDEVALE 1610
SOUTH AFRICA

The mechanicals results, after five years, are not altered in a significant proportion, if stored under recommended conditions*. This allows to use the product hereafter as sterilization wrapping materials within 5 years after its production.

PRODUCT DESIGNATION    CODE
S77 Green                0131000

This information is based on our current knowledge at the date hereof. It applies to the sole product individually referred to herein.

Tuesday, 24 October 2006
Products & Development Director,

C. SIMON

*Recommended conditions of storage:
- Stored in the original packaging (protective polyethylene wrapper)
- Stored in a cool, dry location away from strong light (40 to 80% relative humidity / 50 to 104°F / 10 to 40°C)
- Use the earliest materials received first.
ARJOWIGGINS

TECHNICAL INFORMATION NOTICE
TO SAMD

Address: N°3 Drakensberg Drive
Longmedow West Business Park
Longmedow
ENDEVALE 1610
SOUTH AFRICA

The representative products, of the range in which the following products belong, were have been tested for event-related sterility maintenance study, according to good hospital practises in double layers wrapping. Sterility test results after 180 days are 100% of uncontaminated sites.

<table>
<thead>
<tr>
<th>PRODUCT DESIGNATION</th>
<th>CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Crepe Blue</td>
<td>0075000</td>
</tr>
<tr>
<td>Standard Crepe Green</td>
<td>0067000</td>
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</table>

This information is based on our current knowledge at the date hereof and on the results given by Nelson Laboratories which has performed the test (Report Nber 120345C1 of the 23/02/2000). It applies to the sole products individually referred to herein.

Monday, 10 July 2006
Products & Development Director,

C. SIMON
TECHNICAL INFORMATION NOTICE
TO SAMD

Address: N°3 Drakensberg Drive
Longmedow West Business Park
Longmedow
ENDEVALE 1610
SOUTH AFRICA

The representative products, of the range in which the following products belong, were have been tested for event-related sterility maintenance study, according to good hospital practises in double layers wrapping. Sterility test results after 180 days are 99.2% of uncontaminated sites.

<table>
<thead>
<tr>
<th>PRODUCT DESIGNATION</th>
<th>CODE</th>
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<tbody>
<tr>
<td>S77 Green</td>
<td>0131000</td>
</tr>
<tr>
<td>S77 Blue</td>
<td>0127000</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge at the date hereof and on the results given by Nelson Laboratories which has performed the test (Report Nber 162025B1 of the 12/02/2001). It applies to the sole products individually referred to herein.

Monday, 10 July 2006
Products & Development Director,

C. Simon
Basic Diagram of the inside of an Autoclave
There are four common methods of sterilization used in healthcare today:

- Steam Sterilization
- Peracetic Acid Liquid Sterilization
- Ethylene Oxide Sterilization
- Hydrogen Peroxide Sterilization

### Steam Sterilization

While no sterile processing method is perfect, steam sterilization certainly comes close. It is fast, non-toxic, friendly to the environment and economical. Steam destroys organisms by coagulating the cell protein. In order to destroy all microbes, the steam must be able to come in contact with all surfaces. Steam can only sterilize the surfaces it can touch. For this reason, air pockets are the greatest enemy of the steam process since they prevent the steam from touching all surfaces. Air pockets can occur as a result of improper assembly and loading.

There are two types of steam cycles commonly used: gravity displacement and dynamic air removal, which includes the pre-vacuum and steam flush pressure pulse (SFPP) cycles. Gravity displacement steam sterilization was the first type of cycle introduced to hospitals. Operating rooms still use this type of cycle for “flash” sterilization. The SFPP cycle uses mechanical air removal above atmospheric pressure—these cycles have three phases:

1. **Conditioning Phase**
2. **Exposure Phase**
3. **Exhaust Phase**

The one disadvantage of steam sterilization is that many endoscopes and other delicate devices cannot tolerate high temperatures.
Peracetic Acid Liquid Sterilization

The demand for faster turnaround time for heat-sensitive devices led to the development of Peracetic Acid Liquid Sterilization. Ethylene Oxide gas has been used for years to process heat-sensitive devices, but then the aeration times needed at the end of the cycle to eliminate the gas made this method slow. Peracetic Acid was found to be sporicidal at low concentrations. It was also found to be water soluble, and left no residue after rinsing. It was also shown to have no harmful health or environmental effects. The disadvantages of this method of sterilization are that the devices must be immersible, must fit in the appropriate tray, and must be able to withstand the 55-degree centigrade temperature the process uses.

Ethylene Oxide Sterilization

Ethylene Oxide (EO) is a colorless, odorless, and flammable gas. EO sterilizes through a chemical process known as alkylation. During this process the EO penetrates the microbial cells and reacts primarily with the nuclear material. This results in the cell’s inability to metabolize and reproduce normally. There are many advantages to using EO as a sterilant. It can be used to sterilize items that are incompatible with steam sterilization. It readily permeates and diffuses through commonly used materials, complex devices and lumens because the EO molecule is small. The limitations of EO sterilization are significant. First, the sterilization cycle is much longer than other means of sterilization. Because EO can be harmful to staff and patients, each load requires a lengthy aeration step to ensure that EO is removed from the load. Sterilizers must follow certain requirements for ventilation, exhaust and monitoring because of the safety and
Hydrogen Peroxide Sterilization

This method disperses a hydrogen peroxide solution in a vacuum chamber, creating a plasma cloud. This agent sterilizes by oxidizing key cellular components, which inactivates the microorganisms. The plasma cloud exists only while the energy source is turned on. When the energy source is turned off, water vapor and oxygen are formed, resulting in no toxic residues, harmful emissions or the need for environmental monitoring.

The temperature of this sterilization method is maintained in the 40-50°C range, which makes it particularly well suited for the use of heat-sensitive and moisture-sensitive medical devices. The sterilant chemistry is provided in a self-contained cassette. Depending on the sterilizer model, the sterilization cycle takes between 45-55 minutes. The instruments are wrapped prior to sterilization and can either be stored or used immediately.
Immediately after surgery, rinse instruments under warm running water to remove all blood, body fluids and tissue. If not cleaned immediately after rinsing, instruments should be submerged in a solution of water and neutral pH (7) detergent until they can be cleaned.

- Use stiff plastic cleaning brushes. Do not use steel wool or wire brushes.

- Use only neutral pH (7) detergents. (Low pH detergents, if not rinsed off properly, will cause breakdown of stainless protective surface and black staining. High pH detergents will cause surface deposit of brown stain, which will also interfere with smooth operation of the instrument.)

- Make sure all instrument surfaces are visibly clean and free from stains and tissue.

- Inspect each instrument for proper function and condition. Make sure that scissor blades glide smoothly all the way (blades must not be loose when in closed position). Check that forceps tips are properly aligned. Make sure that hemostats and needle holders do not show light between the jaws, that they lock and unlock easily, and that the joints are not too loose. Check needle holder jaws for wear. Examine cutting instruments and knives to be sure their blades are sharp and undamaged.

- After scrubbing, rinse instruments thoroughly under running water. While rinsing, open and close scissors, hemostats, needle holders and other hinged instruments to ensure that hinge areas are also rinsed out.
• Lubricate all instruments which have any metal-to-metal action such as scissors, hemostats, needle holders, self retaining retractors, etc. Surgical instrument lubricants should be used. Do not use WD-40 oil or other industrial lubricants.

• Instruments may be autoclaved individually or in sets.
  ➢ Individual instruments—Disposable paper or plastic pouches are ideal. Make sure you use a wide enough pouch (4" or wider) for instruments with ratchet locks (such as needle holders and hemostats) so the instrument can be sterilized in an open (unlocked) position.
  ➢ Instrument Sets—Unlock all instruments and sterilize them in an open position. Place heavy instruments on bottom of set (when two layers are required).

• Never lock an instrument during autoclaving. This will prevent the steam from reaching and sterilizing the metal-to-metal surfaces. Furthermore, heat expansion during autoclaving can cause cracks in hinge areas.

• Place a towel on bottom of pan to absorb excess moisture during autoclaving. Make sure the towels contain no detergent residue and are neutral pH (7) when immersed in water. (Laundries frequently use inexpensive but high pH (9-13) detergents and do not properly rinse out or neutralize those detergents in the final wash/rinse cycle. Also, sometimes bleaches are added and are not neutralized.)
Proper care for CSSD Packs

- **Basins and Bowls**
  - Check for sharp edges and cracks.

- **Baskets and Trays**
  - Check for sharp edges; damaged corners and open ends.

- **Linen, Towels and Gowns**
  - Check for tears and holes in the material.

- **Table Surfaces**
  - Check for rough, sharp edges.

*All these factors could tear the Sterilization Paper and therefore compromise the sterility of the packs!*
Items will be loaded within the boundaries of the loading tray so that they do not touch the chamber walls, or fall off when the loading tray is in transit.

Ensure there is sufficient room between items to allow circulation of steam.

Do not overload the chamber.

Racks may be used to allow for adequate separation of packaged instruments.

Packs of hollow-ware and trays of instruments should not be placed above textile packs or soft goods in order to avoid wetting caused by condensation from items above.

Flexible packaging materials, such as pouch bags, will be loaded on edge with paper to laminate, or flat with the paper surface downwards.

Items packaged in flexible packaging materials prone to the entrapment of air and moisture e.g. hollow-ware, will be packed with the opening against the paper and not the plastic.

Do not load the heavier packs on the top shelf as it is easier to unload the packs from the bottom shelf without dragging it.
Unloading of the Autoclave

• On removal of the load the operator will check the print-out or fill in details about the cycle on the record sheet to indicate the required parameters have been met (see monitoring of sterilizer).

• The load should be removed with the proper trolley and the operator should wear gloves to prevent the operator from burning as the packs come out of the autoclave hot.

• Cooling items will not be placed on solid surfaces, as condensation from vapor (still within the pack) may result.

• Do not drag the packs along surfaces as this may result in tears in the packs and compromise the sterility of the pack.
Shelf Life and Rotation of Stock

- Packs wrapped with Medical Paper have a shelf life of 3 months depending on the grade of the paper.
- Instruments packed in steri-pouches remain sterile for +/- 1 year.
- Rotation of stock should be done on a regular basis by rotating your packs from top to bottom, back to front and left to right.
Steam Indicators and Bowie-Dick Test Packs
Sterilization quality control has evolved through time. In 1996, standard ISO 11140-1 was approved by sterilization experts who agreed about an International classification for sterilization chemical indicators.

According to this standard, “class 1” indicators are designed only to indicate that the unit has been exposed to the sterilization process, having a very low level of quality. The most common example of this type is auto adhesive indicator tapes; also, bags and pouches and indicators printed on sterilization packaging.

“Class 4” indicators, this is, “multi - parameter” ones, are designed to indicate critical parameters, but with low precision within the sterilization process. Class 4 indicators are intended to guarantee a defined time of process at a defined temperature, but not with high precision.

“Class 5” (integrators) and “Class 6” (emulators) are intended to integrate all critical parameters of the sterilization process and they are the most reliable choosing for a sterilization quality control. Our sterilization integrators are Class 6 and they are “Wimpy” trademark, available for “steam” and “dry heat” processes. These integrators are manufactured with indicator agents absolutely different from those used for Class 4 indicators. Class 6 integrators are formulated by own inks, researched and developed in our laboratory.

We are going ahead with our researching in order to provide more and more reliable and precise sterilization products.
A multi-parameter indicator is designed to give a fast response in the packs. Its change of colour, indicated on each strip, may be easily interpreted. Multi-parameter indicators are designed to turn under different conditions and indicate stated values of the critical parameters, in the presence of which they change its colour. They are recommended for the internal and external control of packs and containers, but when a better control is required, it is recommended to use sterilization integrators.

**Technical Data:**
- Steam multi-parameter chemical indicator
- Time-temperature-steam indicator designed for use as an external and internal monitor
- Class 4 (ISO 11140-1), class D (UNE-EN 867-1)
- Indicators strips with two reactive seals of 9 x 9 mm.
- The seals change from blue to black after the sterilization process.
- The indicator demonstrates that the unit has been exposed to the steam sterilization process.
- It demonstrates important failures in the sterilization process.
- Material: paper 180 g/m²

![Indicator Image]
Technical Data:

WIMPY™

• Integrator designed to react to all critical parameters of steam sterilization cycles: time, temperature and saturated steam.
• Integrators are placed within a pack/pouch to verify that sterilization conditions have been met at point of placement.
• Class 6 (ISO 11140-1), class D (UNE-EN 867-1)
• Reactive area of 8 cm.
• The green bar changes to black, reference standard printed on each integrator - Easy to interpret.
• Complete colour change in 7.0 minutes at 132-135 ºC (270-275 ºF). Complete colour change in 20 minutes at 121 ºC (250 ºF).
• Green to black colour change is non-reversible.
• Colour change not affected by steam condensation and drying final process.
• Suitable for cycles with drying and flash.
• React only with steam, no reaction present only by heat.
• Material: paper full laminated.
• Easy to file (minimum thickness).

![Not exposed](image1)

![Incorrect, sub-exposed](image2)

![Correct](image3)
Since John Bowie published in 1963 his conclusions on the steam penetration test, - then known as the “Bowie and Dick” test-, this one has been carried out to control the functioning of high vacuum autoclaves. At present, we agree that the disposable test pack method has important advantages over the indicator sheet to be placed in the middle of a standardised clothes pack. Within these advantages we point out the capability to detect the autoclave malfunctioning, when the test is carried out with the empty chamber.

The Bowie & Dick test is Class 2, according to Standard ISO 1140-1 (Class B, according to Standard UNE-EN 867-1) for use in specific tests. A Bowie & Dick test with correct result indicates a correct functioning of the autoclave, but an incorrect result does not necessarily indicate that sterilization have not been reached, but a deficient functioning of the equipment.

Our Bowie & Dick Test Pack was designed to meet the test requirements and includes an indicator sheet to be placed in the centre of the pack, which is interpreted by a comparative results chart aid. The indicator sheet may be used as record and the barrier material is recyclable.

**Technical Data**

**Bowie and Dick Test Pack**

- Air removal test pack.
- Intended to evaluate the performance of the air removal (vacuum) system of Pre-vacuum equipped steam.
- Class 2 (ISO 11140-1), class B (UNE - EN 867 - 1)
- Pre-assembled, disposable test pack.
- After exposure, unwrap pack and remove the indicator sheet for the record.
- Non - reversible light blue to black colour change. Easy to interpret.
Single use BOWIE & DICK type autoclave TEST PACK

COMPARISON CHART

UNEXPOSED
Light green original colour

INCORRECT - LOW TEMPERATURE
Steam penetrates the pack, but temperature is very low

INCORRECT - POOR PENETRATION OF STEAM
Intense colour at edges and light colour in the centre, show that steam cannot penetrate into the pack

INCORRECT - POOR PENETRATION OF STEAM
Steam penetration is almost complete, but some zones, usually in the centre, are light coloured

CORRECT
Uniform dark brown-black final colour shows that sterilizer is working correctly
This will be placed at the back of the Bowie Dick for record keeping purposes
CERTIFICATE

IQNet and
IRAM
hereby certify that the organization

QUIMICA DEL SANTO S.A.
Belgrano 4676 (B1650CDF) – San Martin – Pcia. Bs. As. – Argentina

for the following field of activities

Sterilization chemical indicators design, manufacture and marketing

has implemented and maintains a

Management System

which fulfills the requirements of the following standard

ISO 9001:2000

Issued on: 2004-09-21
Validity date: 2007-09-21

Registration Number: AR-QS-1141

Dr. Fabio Roversi
President of IQNet

Ing. José Francisco López
General Director of IRAM
PRODUCT CLASSIFICATION CERTIFICATE

Trade mark of the item: VISTO BUENO

Description of the item: STEAM MULTIPARAMETER CHEMICAL INDICATOR

We hereby declare that sequential examination has been carried out following the requirements of the ISO 11140-1, and EN 867-1 which are relative to classification of chemical indicators.

We certificate that the aforementioned chemical indicator covers the feature of class 4 accordance with ISO 11140-1, as well as Class D, respect to EN 867-1

[Signature]

GUSTAVO LUIS ENRIQUEZ
DIRECTOR TECNICO
MATR. 2526 - M.P. 15407
PRODUCT CLASSIFICATION CERTIFICATE

Trade mark of the item: VISTO BUENO

Description of the item: TEST PACK BOWIE & DICK

We hereby declare that sequential examination has been carried out following the requirements of the ISO 11140, and EN 867 which are relative to classification of chemical indicators.

We certificate that the aforementioned chemical indicator covers the feature of class 2 accordance with ISO 11140, as well as Class B, respect to EN 867.

[Signature]
Firm. GUSTAVO LUIS ENRIQUEZ
DIRECTOR TECNICO
M.N. 17524 - M.P. 15407

ASISTHOS S.R.L. Calle 23 N° 1442 - Villa Maipú (1650) - San Martín - Buenos Aires - Argentina
Tel./Fax: 4713-1681 (Rotativas) E-mail: info@asisthos.com.ar
PRODUCT CLASSIFICATION CERTIFICATE

Trade mark of the item: VISTO BUENO

Description of the item: STEAM STERILIZATION INDICATOR

We hereby declare that sequential examination has been carried out following the requirements of the ISO 11140-1, and EN 867-1 which are relative to classification of chemical indicators.

We certificate that the aforementioned chemical indicator covers the feature of class 4 accordance with ISO 11140-1, as well as Class D, respect to EN 867-1.
PRODUCT CLASSIFICATION CERTIFICATE

Trade mark of the item: VISTO BUENO

Description of the item: STEAM INTEGRATING INDICATOR

We hereby declare that sequential examination has been carried out following the requirements of the ISO 11140-1, and EN 867-1 which are relative to classification of chemical indicators.

We certificate that the aforementioned chemical indicator covers the feature of class 5 accordance with ISO 11140-1, as well as Class D, respect to EN 867-1