

To do a job right, dress right

Single-use nonwovens for medical wear

Hygiene and safety meeting the new EN 13795 standard





Bad news for traditional linen as new infection control standards come into force

A long-awaited European standard covering the safety performance of drapes, gowns and clean air suits in the operating theatre has finally come into force, and many hospitals will need to make some drastic changes.

Many linen drapes and gowns do not meet the requirements of the standard (EN 13795), and hospitals that continue to use such linen in their operating theatres will be taking a huge gamble. The standard is the European-wide agreed method for demonstrating that drapes and gowns meet the safety requirements of medical devices legislation. Hospitals using possibly non-compliant products must ensure their suppliers can still meet these safety requirements.

Single-use nonwovens drapes and gowns ensure that hospitals comply with the standard, provided the products have been duly certified by their manufacturers. The common consensus is that single-use nonwovens deliver the most adaptable protection from infection in the operating theatre. New diseases require cutting-edge solutions to protect staff and patients, and only precision-engineered materials such as nonwovens can both provide a sterile barrier and meet the other key requirements of the standard, such as minimal linting.

The standard represents a great leap forward for hospital safety, as it has been documented for many years that under surgical conditions traditional linen does not provide an effective barrier to transmission of infection between patients and clinical staff.¹

Hospitals using linen drapes and gowns will have to act immediately to prepare for the change. They will have to make a choice: what type of drapes and gowns provide the necessary level of protection for the best value?

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¹ Moylan, J. A., Kennedy, B. V. "The importance of gown and drape barriers in the prevention of wound infection." *Surgery, Gynecology & Obstetrics* (1980) 151:4: 465-470.

Werner, H. P., Felten, M., and Schmitt, O. "Quality of surgical drapes and gowns." *Hyg Med* (2001) 26 : 63-75.

EN 13795 - what is it all about?

What does it apply to?

- ✿ Theatre patient and equipment drapes, surgical gowns and clean air suits, whether they are supplied as stand-alone products or included in procedure trays.

When will it come into force?

- ✿ The harmonised standard has already been cited in the Official Journal of the European Union, and it is being awaited for all EU Member States to comply with the standard.

Why is it necessary?

- ✿ Better protection for patients and staff. Drapes and gowns must protect against penetration of infectious micro-organisms and bodily fluids.

What is a harmonised European standard?

- ✿ Harmonised standards are agreed collectively by representatives from all EU Member States. A European standard sets out the technical specifications that allow manufacturers to ensure their products meet the Essential Requirements of particular legislation, in this case the EU Medical Devices Directive (93/42/EEC).

What are Essential Requirements?

- ✿ The Essential Requirements describe the necessary properties that have to be fulfilled for a product to be considered safe and fit for use. They cover both product design and manufacture and include general safety, chemical, physical and biological requirements, microbiological aspects and labelling.

Do all drapes and gowns have to comply with the standard?

- ✿ Companies who want to legitimately claim that their products meet these Essential Requirements should refer to the fact that they comply with the standard, because the standard allows both companies and end-users to presume that – within the limits of the scope of the standard – the products meet these Essential Requirements. If not, then companies must find alternative methods to demonstrate that they can meet them.

How is this standard related to existing legislation?

- ✿ Compliance with the standard allows both companies and end-users to presume that – within the limits of the scope of the standard – products conform to the EU Medical Devices Directive.

How do I know if a product complies with the standard?

- ✿ Products that comply with the standard should bear the CE mark.

Nonwovens: hi-tech infection control

The operating theatre is a sensitive environment that must be carefully managed – patients are at their most vulnerable, and hospital staff are directly exposed to potential sources of infection. Gowns and drapes play a critical role as barriers to minimise the spread of infective agents to and from patients' operating wounds.

Nonwovens are unique engineered fabrics – strong, yet light and comfortable. Advanced production methods are used to create a range of nonwovens whose qualities can be specified to meet particular needs.

It has been documented for years that under surgical conditions, traditional linen is not a barrier to the spread of micro-organisms, especially by liquids.² Unlike modern fabrics such as nonwovens, linen provides inadequate protection to patients and staff.

Medical nonwovens combine phenomenal barrier properties with other key qualities. A high level of breathability ensures comfort for wearers, self-adherent edges ensure precision in isolating the wound, and aseptic folding and a low level of linting help protect the sterile operating environment.

Manufacturing techniques are constantly evolving to make nonwovens even more effective as barriers to the spread of infection. As one example, electrostatic spinning is used to create nonwoven webs that are tight enough to resist penetration by 'E. coli' bacteria. These webs have filaments less than one thousandth of a micron in diameter. 'E. coli' bacteria are typically two microns long by one micron diameter.

The adaptability of single-use nonwovens ensures the most appropriate level of protection for both patients and medical staff for every single procedure.

² Moylan, J. A., Kennedy, B. V. "The importance of gown and drape barriers in the prevention of wound infection." *Surgery, Gynecology & Obstetrics* (1980) 151:4: 465-470.
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Benefits of single-use

Single-use nonwovens products offer end-users complete confidence and security, as they give the same outstanding level of barrier protection to every single procedure. Given that wound infections are the cause of over one third of post-operative deaths, it is clear that the importance of single-use products in preventing transmission of infection in the operating theatre cannot be overestimated.

With single-use products, end-users don't have to worry about legal liability – responsibility for ensuring products are safe lies with the manufacturers, provided they are only used for one surgical procedure before disposal. Theatre staff need only to ensure the integrity of the packaging and check the contents of the package.

Choosing single-use drapes and gowns also means simpler logistics. There are 3 steps for single-use: you buy it; you use it; you dispose of it. Hospital staff using single-use products save time and expense, as there is no need to co-ordinate the re-processing of soiled drapes and gowns.

Single-use products make theatres more efficient – innovations such as custom-made packs for specific procedures save theatre staff precious time, and allow them to concentrate on other important tasks.

Budget-friendly infection control

Single-use products have no hidden costs such as laundering, repairing, re-sterilising or re-packaging. The full cost of single-use drapes and gowns is known for every procedure, every time.

Single-use nonwovens save hospitals huge sums of money by preventing the spread of healthcare associated infections (HCAI) in the operating theatre. HCAI are a huge drain on hospital resources, affecting an estimated 1 in 10 patients. Single-use nonwovens are a vital tool in fighting transmission of HCAI during surgery.

Single-use drapes and gowns also give hospitals the flexibility to choose the right draping for every procedure. Drapes and gowns can be chosen against a range of criteria to ensure that they provide the right level of protection at the right price.



Nonwovens industry

Meeting your needs

The EN 13795 standard represents a great leap forward for safety in hospitals across Europe. The nonwovens industry will help European hospitals implement the standard as painlessly as possible.

Medical companies offer customers a range of services to help manage the transition to single-use products. Many companies have clinically-trained sales staff with first-hand experience of the practical challenges of the operating theatre, while many companies also offer training courses to theatre staff on using the new products.

The nonwovens industry is committed to maintaining constant dialogue with medical staff to ensure that products meet the healthcare community's expectations. Medical companies will keep developing innovative materials and products to manage the ever-changing threat from clinical infection.

Environmental stewardship

The nonwovens industry actively manages the environmental impact of its products across their entire lifecycle. Examples include:

1. Planting trees to replace the wood used to manufacture certain types of nonwovens.
2. Recovering end-of-life nonwovens into energy – incineration of nonwovens, respecting environmental standards, can provide energy for central heating and hot water.
3. Manufacturing sites signing-up to internationally-recognised environmental management programmes such as EMAS (Eco-Management & Audit Scheme), and publishing data on their environmental performance.
4. Continuously identifying opportunities to reduce the environmental footprint of the nonwovens industry – for example, recycling water used during the production of the “hydro-entangled” nonwovens used for certain drapes and gowns.

This brochure is designed to help healthcare professionals evaluate their options in the light of the EN 13795 standard. It is produced by Medeco, the Medical Devices Committee of EDANA, the voice of nonwovens in Europe.

For more information about the CEN standard, please visit www.medeco.edana.org.



About EDANA

Unifying the diversified interests of over 210 member companies in 30 countries, EDANA is the international association serving the nonwovens and related industries.

Medeco's mission is to increase awareness of the benefits of nonwovens in healthcare, and to bring single-patient solutions from the nonwovens industry to the decision-makers, specifiers and end-users in surgery, wound management and infection control.

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Kimberly Clark
Mölnlycke
3M
Dupont

edana

Published by EDANA
International Association Serving
the Nonwovens and Related Industries
157, Avenue Eugène Plasky
B-1030 Brussels, Belgium
Tel: +32 2 734 93 10
Fax: +32 2 733 35 18
e-mail: info@edana.org

www.edana.org
www.medeco.edana.org

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