A COMMON LANGUAGE TO COMPARE PRODUCT PERFORMANCE

Standards for medical devices aim at improving the quality of the products on the market and are therefore vital for good clinical practice.

The European Standard EN 13795 is the first standard for users and suppliers of single-use and multiple-use products, with mutually agreed test methods to be applied to all fabrics on the market, irrespective of their construction. This standard provides an excellent tool for users to compare product performance. EN 13795 is an EU recognized harmonized standard.

EN 13795 SPECIFIES REQUIREMENTS FOR SINGLE-USE AND REUSABLE SURGICAL DRAPES (INCLUDING EQUIPMENT COVERS AS STERILE FIELD), SURGICAL GOWNS AND CLEAN AIR SUITS.

The standard sets out the technical requirements of the products, responsibilities of manufacturers, processes and provides information for the use of their devices, intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures.

In order to comply with EN 13795, the devices have to meet a number of technical requirements as demonstrated by the following test conditions.
RESISTANCE TO DRY MICROBIAL PENETRATION (EN ISO 22612)

Objective: determine the ability of the dry fabric to resist penetration of particles carrying micro-organisms.
Method: the test fabric is placed in a container with talc contaminated with Bacillus subtilis. Any talc that penetrates the fabric is captured on a sedimentation plate underneath and incubated.
Measure: number of colonies formed after incubation.

RESISTANCE TO WET MICROBIAL PENETRATION (EN ISO 22610)

Objective: determine a fabric's resistance to penetration of bacteria in a liquid while being subjected to mechanical rubbing.
Method: the test fabric is subjected to material contaminated with Staphylococcus aureus suspension. If penetration occurs, bacteria will collect on to an agar surface and be incubated.
Measure: number of colonies formed after incubation, expressed in Barrier Index (BI).

RESISTANCE TO LIQUID PENETRATION (EN 20811)

Objective: estimate the resistance of fabrics to liquid penetration by water under constantly increasing hydrostatic pressure.
Method: one side of the fabric sample is subjected to purified water pressure which is increased at a constant rate until leakage appears on the other side of the fabric sample.
Measure: the head height results are recorded in centimeters of water pressure on the fabric sample.

CLEANLINESS

CLEANLINESS – MICROBIAL (EN ISO 11737-1)

Objective: estimate the bioburden or number of viable micro-organisms on a product prior to sterilisation.
Method: stomaching method – EN ISO 11737-1 B.2.2.1.
Measure: number of colonies formed (per dm²).
CLEANLINESS – PARTICULATE MATTER

**Objective:** estimate linting of the fabric in a dry state, prior to twisting and compressing.

**Method:** fabric is placed in a chamber and number particles are calculated.

**Measure:** number of particles from 3μm to 25 μm, as an index for Particulate Matter (PM) expressed as log_{10}.

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LINTING

**Objective:** estimate linting of the fabric in a dry state, after twisting and compressing.

**Method:** the same fabric sample is twisted and compressed.

**Measure:** number of particles from 3μm to 25μm generated after the twisting and compressing, expressed as log_{10} of the count value.

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STRENGTH

BURSTING STRENGTH – DRY & WET (EN 13938-1)

**Objective:** determine the resistance of a fabric to puncture under dry and wet conditions.

**Method:** a fabric sample is clamped over an expansive diaphragm by means of a circular ring. Fluid pressure is applied at a constant rate on the other side of the diaphragm causing distension of the diaphragm and fabric until the fabric bursts.

**Measure:** strength at burst, in kPA.

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TENSILE STRENGTH – DRY & WET (EN 29073-3)

**Objective:** determine the ability of a product to withstand fabric tearing under dry and wet conditions.

**Method:** a strip (specified length and width) of fabric is held in place with clamps on a machine that pulls the strip apart at a constant rate of extension.

**Measure:** amount of force applied to break the strip, in Newton.

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C = Critical Area    LC = Less Critical Area
WHAT IS THE SIGNIFICANCE OF EN 13795 ON HEALTHCARE FACILITIES THAT ACQUIRE SINGLE-USE OR MULTIPLE-USE GOWNS AND DRApes FROM EXTERNAL SUPPLIERS?

As always, the healthcare facility should verify that the device is CE marked (i.e. meets the requirements of the Medical Device Directive). Should the manufacturer claim compliance to EN 13795, the customer can request the test data.

ARE HOSPITALS OBLIGED TO PURCHASE DEVICES THAT COMPLY WITH THE STANDARD?

No, as standards are in itself voluntary, manufacturers have the choice to determine their own conformity assessment route. However, in the case of EN 13795, most manufacturers claim compliance to the standard. Customers are always advised to request documentation on performance from all manufacturers independently from them claiming compliance to EN 13795 or not.

WHAT FACTORS DOES A HOSPITAL HAVE TO CONSIDER WHEN CHOOSING DRApes AND GOWNS?

If hospitals utilize products that are not in compliance with applicable European or International standards, they would need to substantiate their decision, and the burden of proof is upon the hospital in the event of an inspection, a medical complaint or any other issues. Therefore, in terms of product liability hospitals would want to use products/devices that comply with International or European standards.

ALL HALYARD® DRApes AND GOWNS EXCEED THE MINIMUM PROPOSED PERFORMANCE REQUIREMENTS LISTED IN EN 13795

For more than 40 years, Halyard Health (formerly known as Kimberly-Clark) has been recognized as a leader in the development of surgical fabrics of outstanding performance and reliability, with over 650 patents registered for advanced nonwoven fabrics. When choosing HALYARD® Surgical Drapes and Gowns, you know you’re getting a trusted clinical solution for a wide range of surgical procedures.

For more information, please send an email to customerservice.uk.ie@hyh.com or visit www.halyardhealth.co.uk.