HOHENSTEIN

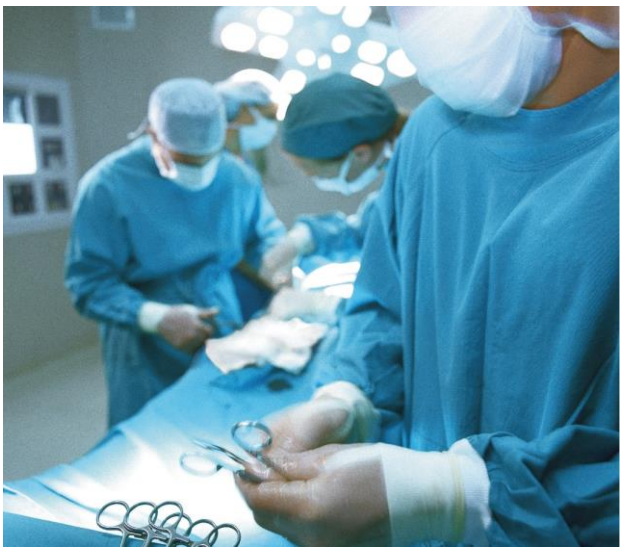
Quality assurance for surgical textiles – DIN EN 13795-1

Objective

Meeting the performance requirements of single-use and reusable surgical drapes and gowns for use as medical devices as specified in European Standard 13795-1:2019.

Your benefit as a customer

- Proof of the performance requirement
- Proof of conformity of the product with the Medical Device Regulation (prerequisite for CE marking)



Description

Particularly high demands are placed on surgical textiles. The transfer of infectious agents between hospital staff and patients during surgical and other invasive procedures should be minimised as far as possible. By meeting basic requirements, the textiles contribute to the general safety for patients.

Biological tests

- Evaluation of germ penetration in dry state (EN ISO 22612)
- Evaluation of germ penetration in wet state (EN ISO 22610)
- Evaluation of microbiological cleanliness/bioburden (EN ISO 11737-1)
- *optional*: Evaluation of biocompatibility (EN ISO 10993-1; i.e. cytotoxicity DIN EN ISO 10993-5, chemical characterisation DIN EN ISO 10993-18)

Physical tests

- Evaluation of particle release (EN ISO 9073-10)
- Evaluation of liquid penetration (EN ISO 811)
- Evaluation of burst strength in dry and wet condition (EN ISO 13938-2*)
- Evaluation of tear strength in dry and wet condition (EN 29073-3)

*) Deviating from the requirement standard DIN EN 13795-1, the burst strength is not carried out according to EN ISO 13938-1, but according to EN ISO 13938-2. EN ISO 13938-1 section 1 indicates that there is no significant difference in the bursting strength results achieved using tests according to EN ISO 13938-1 (hydraulic method) and EN ISO 13938-2 (pneumatic method) for pressures up to 800 kPa.

Test sample requirements

General

- Depending on the customer's requirements, biological and/or physical tests can be carried out in the new state or after a defined number of reprocessing cycles

Quantity of material

- approx. 5-10 ready-made parts, but with at least 4 m^2 of the relevant area of the test sample (if all tests are ordered)

Duration of test

- in general 4-6 weeks: confirmation of date after receipt of test sample