# Microbial Barrier Tests for Sterile Barrier System (i.e. : Sterilization Wraps)

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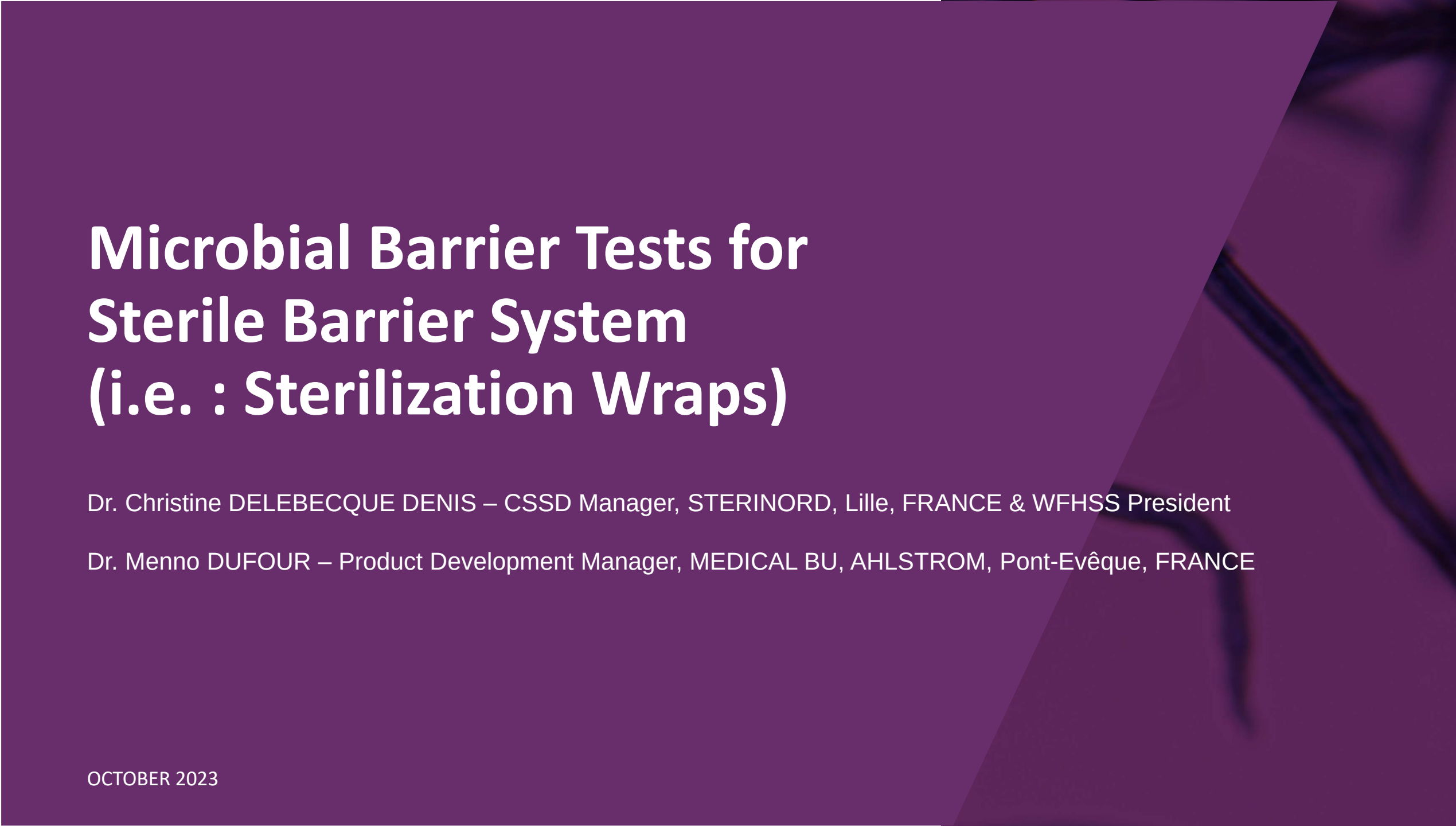

OCTOBER 2023

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- ISO 11607-1 Standard and microbial barrier tests
- DIN Tests : DIN 58953-6
  - Testing of Crepe, SMS and Textile (“Linen”) & Conclusions
- Recommendation of the WFHSS
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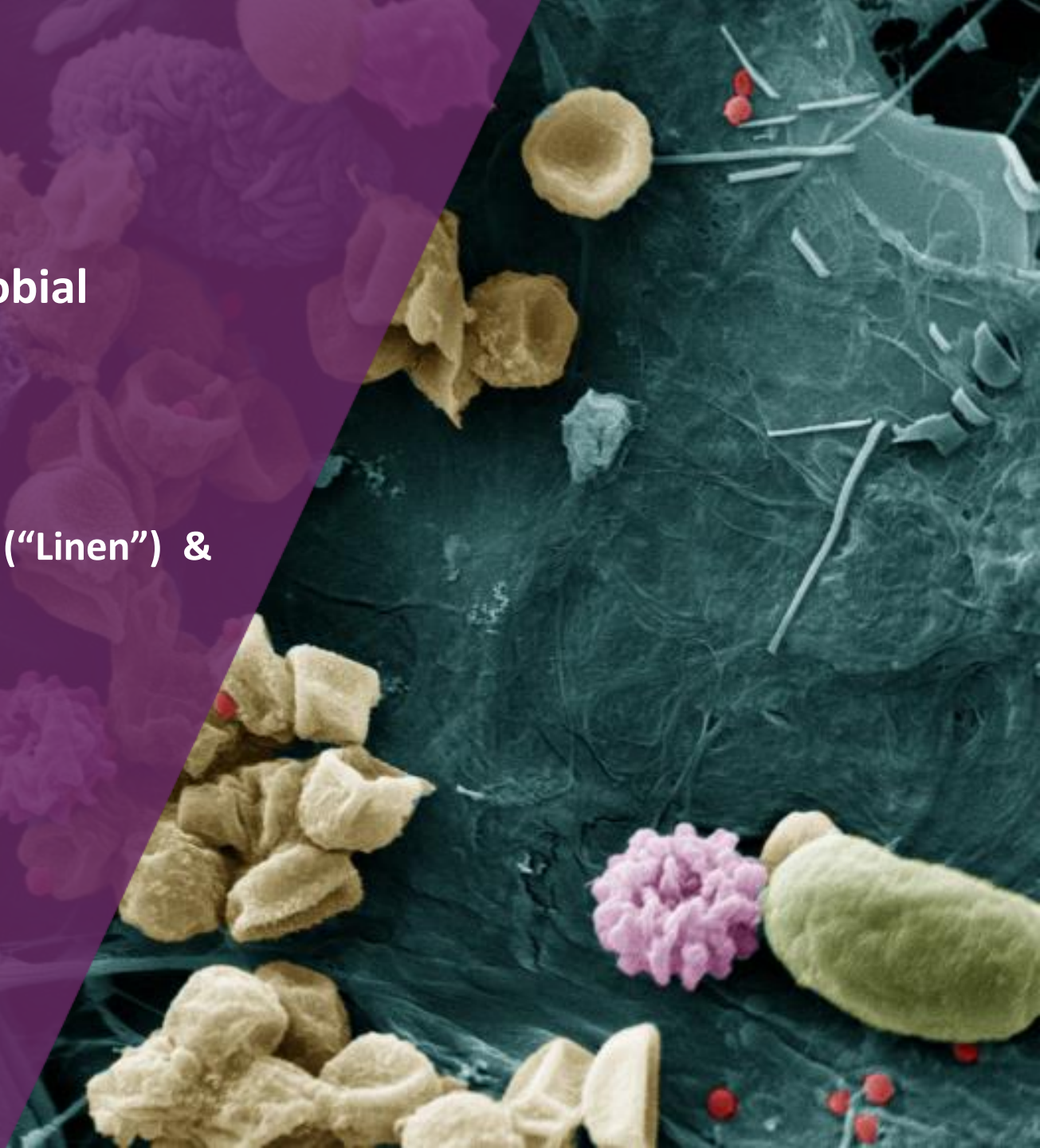


# Microbial Barrier Tests for Sterile Barrier Systems according to ISO 11607-1

INTERNATIONAL STANDARD **ISO 11607-1**

Second edition
2019-02

**Packaging for terminally sterilized medical devices —**

Part 1:
**Requirements for materials, sterile barrier systems and packaging systems**

*Emballages des dispositifs médicaux stérilisés au stade terminal —*

*Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage*

**5.2 Microbial barrier properties**

**5.2.1** If not a declared porous material, the impermeability shall be determined in accordance with Annex C.

NOTE The microbial barrier properties of materials used in the construction of sterile barrier systems are critical for ensuring integrity and product safety. The methods used for evaluation of the microbial barrier properties are divided into two categories: those that are appropriate for impermeable materials, and those that are appropriate for porous materials.

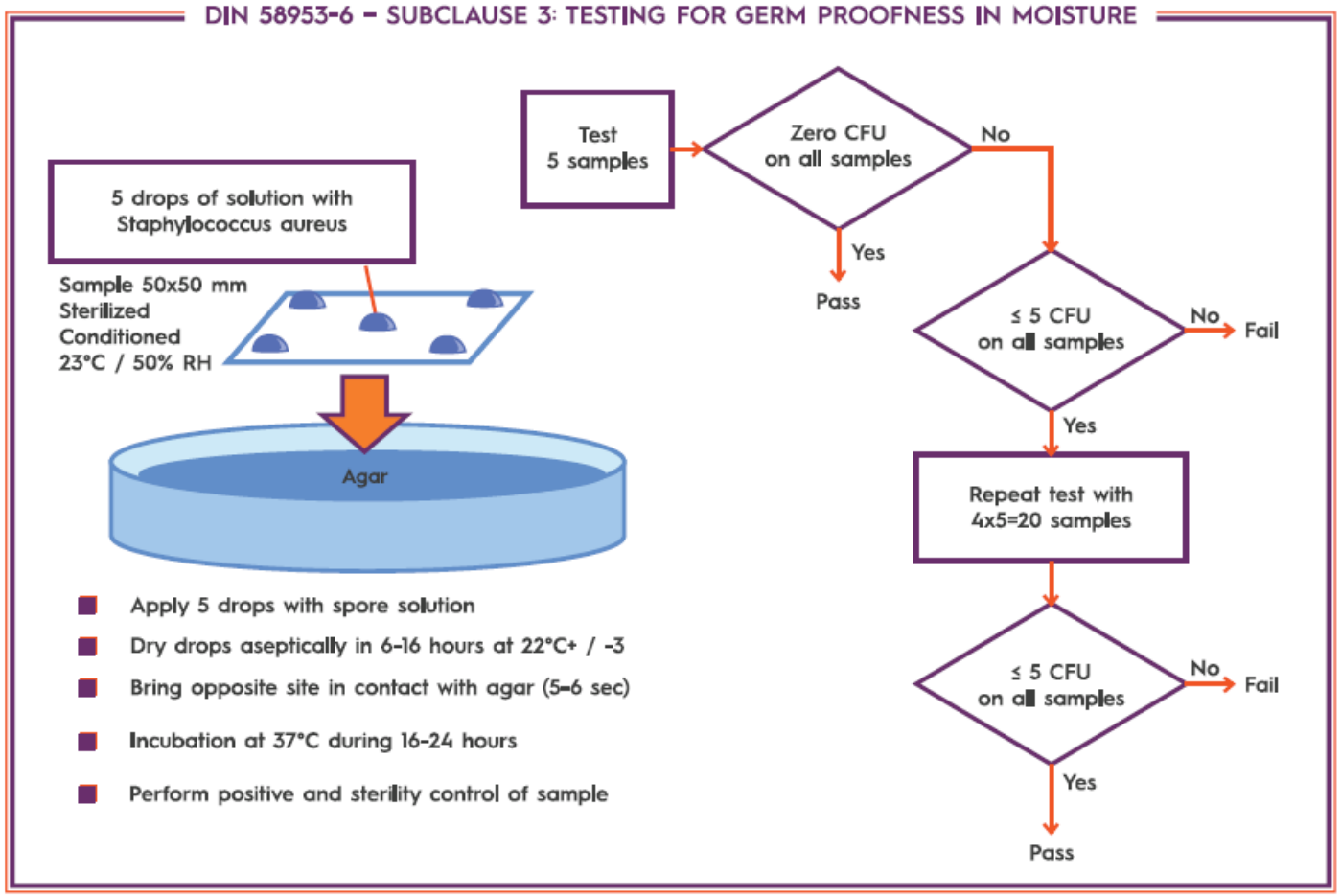
**5.2.2** A demonstration that the material is impermeable shall satisfy the microbial barrier requirement.

**5.2.3** Porous materials shall provide an adequate microbial barrier to microorganisms.

**Table B.1** *(continued)*

| Attribute/ Characteristics | Reference | Title of reference | Test method has statement of precision and/or bias, repeatability and reproducibility | Test method only has statement of precision and/or bias | Guidance, Standard Practice |
|---|---|---|---|---|---|
| **Microbial barrier** | DIN 58953–6 | Sterilization — Sterile supply — Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized; subclause 3: Testing for germ proofness in moisture and subclause 4: Testing for germ proofness with passage of air | Yes | — | NA |

# DIN Tests – Germ Proofness in moisture (Wet) – Section 3




- If 0 CFU on 5 samples tested, then test is passed
- If sum of CFU on 5 samples is ≤ 5 CFU : need to run Re-examination on 20 samples
- If Re-examination is done (testing 20 samples), maximum is 5 CFU for 20 samples.

→ Test Results : **Pass** / **Fail**

# DIN Tests – Germ Proofness with passage of air (Dry) – Section 4

DIN 58953-6 – SUBCLAUSE 4: TESTING FOR GERM PROOFNESS WITH PASSAGE OF AIR

## Microbiological

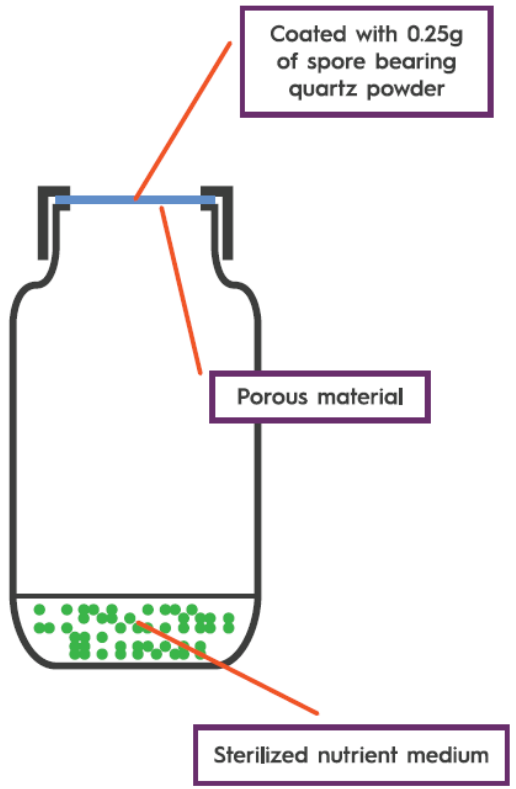
- Bacillus subtilis variant globigii spores coated on powdered quartz with a grain size of 0.04 – 0.15 mm

## Test Conditions

- Heat to 50°C and cool to 10°C five times (oven and refrigerator)
- No vibration
- Face velocity (theoretical) – 0.60 cm/min

## Evaluation

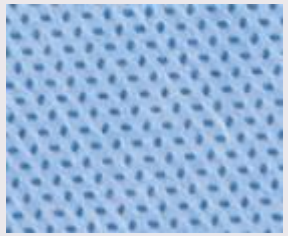
- Max 15 CFU on the 10 samples
- Max 5 CFU per sample
- Test result = pass/fail

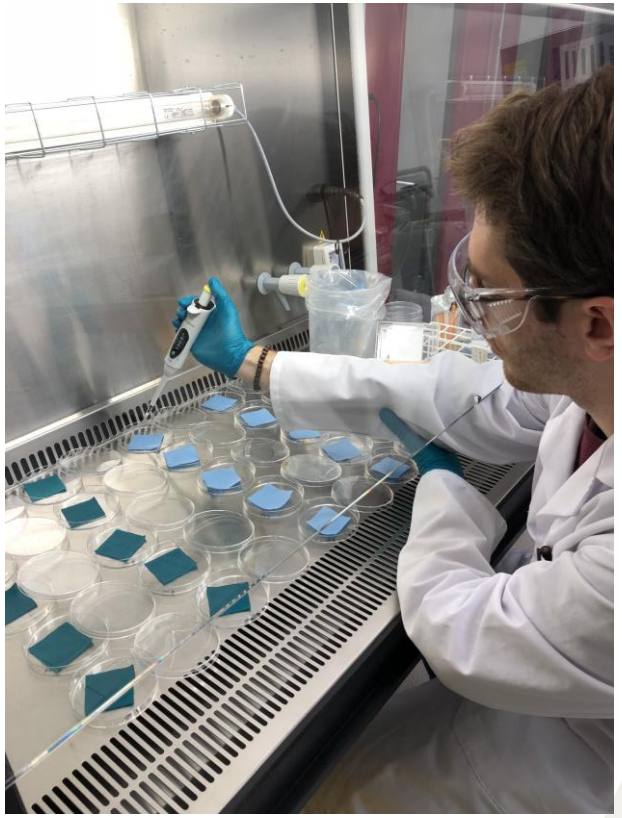



- The bottles are alternately warmed (incubator 50°C) and cooled (refridge 10°C) in order to build up an air stream within, done 5 times
- Due to this air flow the bacteria are expected to come onto agar
- Incubate for 37°C for 24h.

→ Test Results : **Pass** / **Fail**

# Results – DIN tests (Done in *In-House* Microbiology Lab)

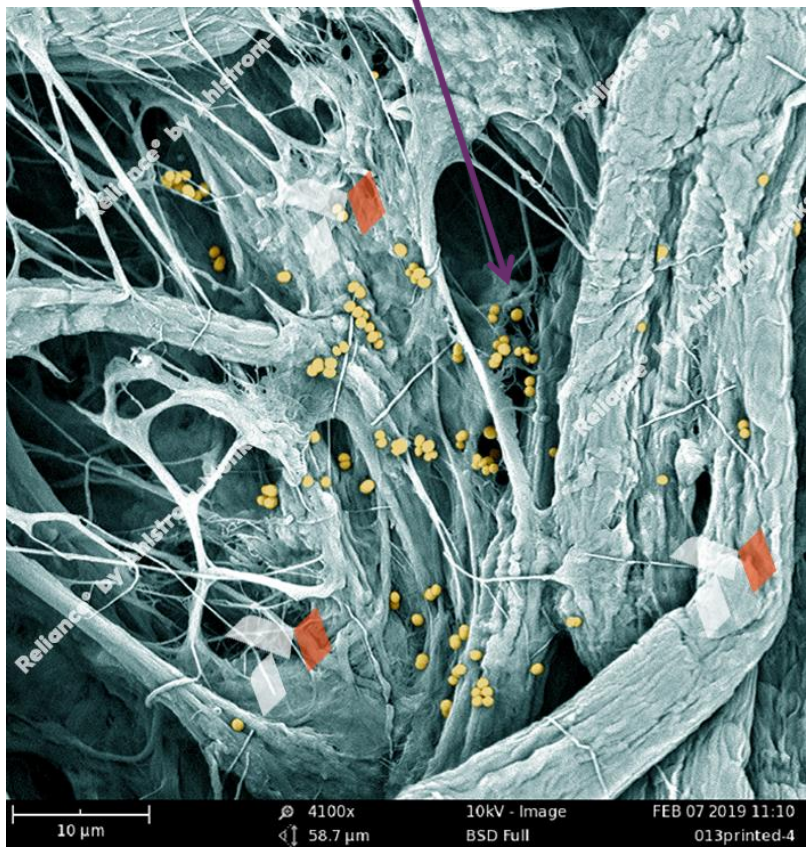
| Sample (after steam sterilization) | DIN Humid | DIN Dry |
|---|---|---|
| **Crepe paper**<br>Thickness : 120 µm<br>Basis Weight : 60 g/m²  | Pass | Pass |
| **SMS**<br>Thickness : 220 µm<br>Basis Weight : 43 g/m²<br>(or more heavy weight)  | Pass | Pass |
| **Textile (“Linen”)***<br>Thickness : 300 µm<br>Basis Weight : 170 g/m²  | Fail | Fail |



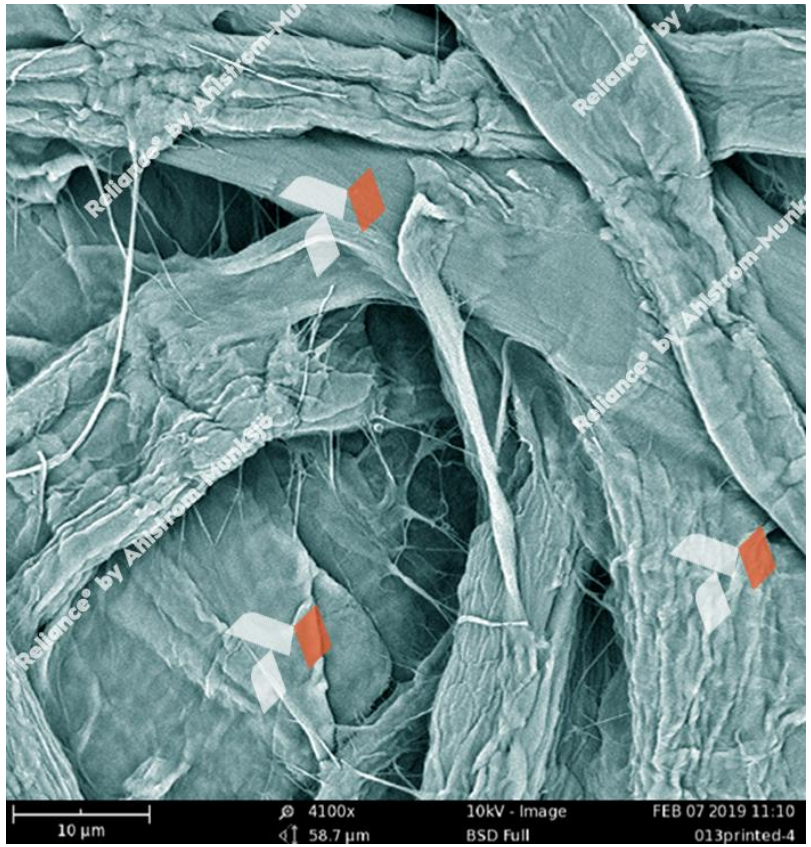
*Textile (« i.e. : Linen ») was washed one time in a washing machine at 60°C

# SEM Picture of DIN test in Humid Conditions – Crepe Paper

*Inoculated Side with Bacteria (Staphylococcus aureus)*



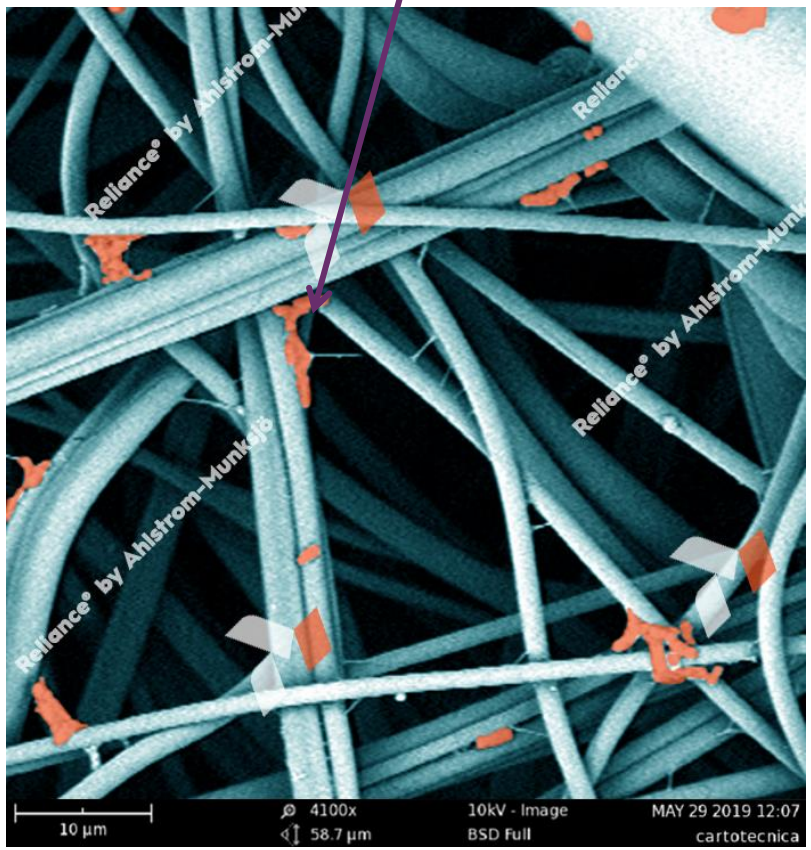

*Back Side (No Bacteria)*




- Crepe Paper is considered as sufficiently germ proof as per DIN 58 983-6 (Bacteria are staying onto inoculated side and does not go through the material, other side is free of Bacteria: ***Sterile Barrier System***) : **Pass**

# SEM Picture of DIN test in Dry Conditions – SMS Material

*Inoculated Side with Bacteria (Bacillus subtilis)*

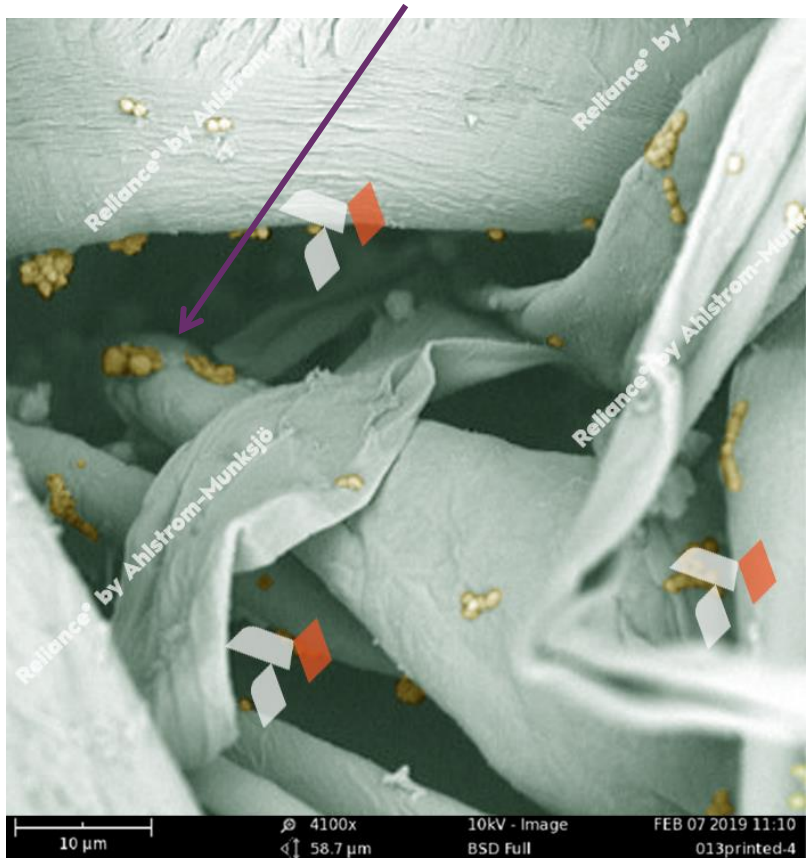



*Back Side (No Bacteria)*

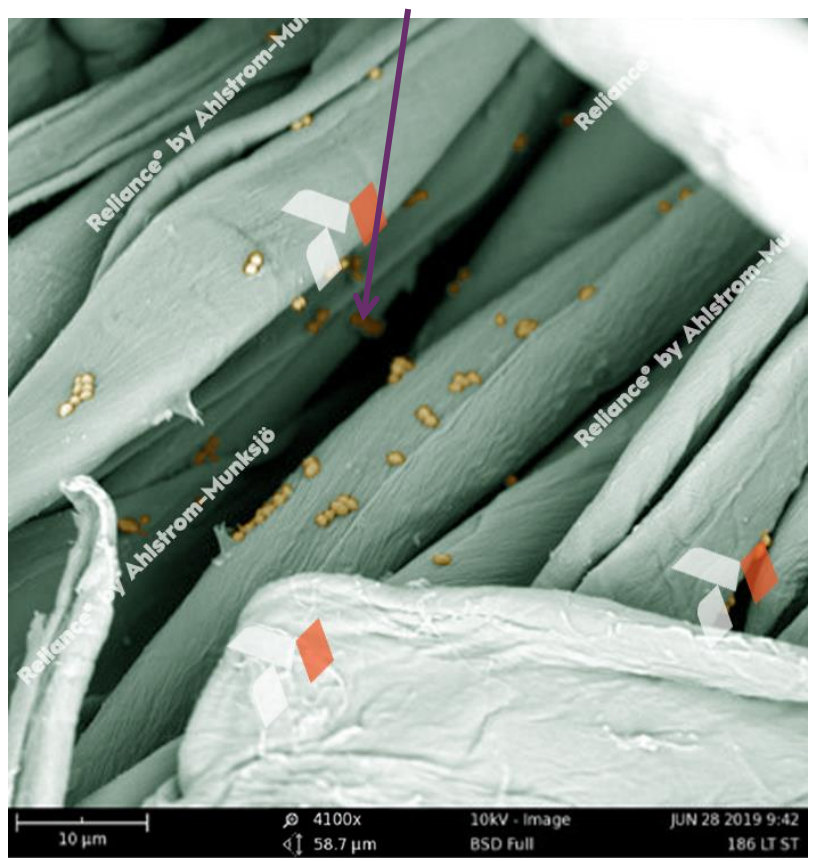

- SMS material is considered as sufficiently germ proof as per DIN 58 983-6 (Bacteria are staying onto inoculated side and does not go through the material, other side is free of Bacteria: ***Sterile Barrier System***) : **Pass**

# SEM Picture of DIN test in Humid Conditions – Textile (“Linen”)

*Inoculated Side with Bacteria (Staphylococcus aureus)*




*Back Side (Bacteria)*




- Textile is not considered as sufficiently germ proof as per DIN 58 983-6 (Bacteria are going through the material during the test, contaminating the other side, ***not a Sterile Barrier System***): **Fail**

# Conclusions

**According to DIN Tests : DIN 58953-6 : 2016-12**

- Crepe and SMS are **sufficiently** germ proof (**Pass**)
- Textile (“Linen”) is **not sufficiently** germ proof (**Fail**)

**Results confirmed at third party lab (i.e. ISEGA, Germany)**
**See below results of textile (i.e. : “Linen”) :**

**Determination of Germ Proofness under Humidity * and with Air Permeance***

The determination was performed according to DIN 58 953-6:2016-12, section 3 (germ proofness under humidity) and section 4 (germ proofness with air permeance). After sterilization by steam (134 °C / 4 min) the sample was contaminated with the test germ on the both material sides.

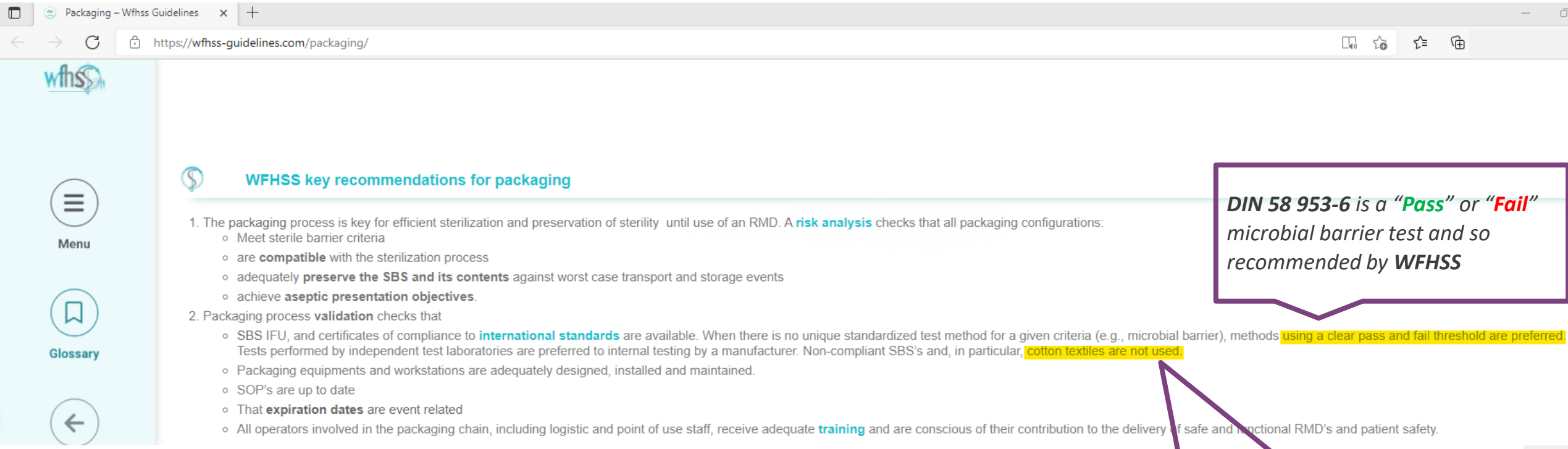
Result:

| Germ proofness under humidity | | | | | | |
|---|---|---|---|---|---|---|
| Sterilization - Test side | Number of CFU / agar plate | | | | | |
| | 1 | 2 | 3 | 4 | 5 | Σ |
| Steam (134 °C) - Side A: | n.c. | n.c. | n.c. | n.c. | n.c. | **n.c.** |
| Steam (134 °C) - Side B: | n.c. | n.c. | n.c. | n.c. | n.c. | **n.c.** |

| Germ proofness with air permeance | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Sterilization - Test side | Number of CFU / specimen | | | | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | Σ |
| Steam (134 °C) - Side A: | 68 | 20 | 33 | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | n.c. | **n.c.** |
| Steam (134 °C) - Side B: | 74 | 51 | 68 | 37 | 20 | 22 | 69 | 86 | n.c. | n.c. | **n.c.** |

CFU = Colony forming unit / n.c. = not countable

# Recommendation of the WFHSS (World Federation for Hospital Sterilization Sciences)




***DIN 58 953-6*** *is a "**Pass**" or "**Fail**" microbial barrier test and so recommended by* ***WFHSS***

*The use of **textile ("linen")** for packaging is **prohibited** because they do not constitute a sufficient microbial barrier and are sources of particulate contamination."*

https://wfhss-guidelines.com/packaging/

## Linen/textiles:

It is not a microbial barrier !!!

FORBIDDEN in a lot of countries like in Europe / USA

+ Bring particles (dust) in CSSD and OR

+ deposit of residual laundry compounds on instruments while sterilization

# Linting (ISO 9073-10)

**Linting: generation of particle higher than 3 µm is an important topic in the medical field as such particles are a way for micro-organism to travel from one point to another**

- Linting is being tested using the Gelbo Flex Tester according to ISO 9073-10 (see YouTube video for more details)
- Linen is generating 20 times more lints than crepe paper and 1000 times more lints than SMS (tests done at CENTEXBEL, Belgium)
- Linen is then generating a huge amount of particles that will allow micro-organism to contaminate Sterile Reusable Medical Device and could therefore generate Healthcare Acquired Infection

Gelbo Flex Tester with Sample Preparation and complete Testing Method - YouTube

# Thank You

OCTOBER 2023