

Organizer:

Sterile Barrier Association (SBA)
Mr. Dave Harding (Director General)
director.general@sterilbarrier.org

Performance:

VFV - Verein zur Förderung der Forschung
und Ausbildung für Faserstoff-
und Verpackungswissenschaften e.V.

Technical realization:

ISEGA Forschungs- und Untersuchungsgesellschaft mbH
Mr. Dr. Derra / Mrs. Dr. Julia Riedlinger / Mr. Daniel Zahn
Zeppelinstraße 3-5, 63741 Aschaffenburg / Germany, info@iseqa.de

Occasion and aim of the round robin test:

In the course of the planned revision of the ISO 11607-1:2006 „Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems “ all standards listed in appendix B will presumably be classified into different categories, namely into test methods with precision and bias statement and into methods without those validation data.

Due to this new structuring it is likely to happen that the DIN 58953-6: 2010 „Sterilization – Sterile supply – Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized“, which does not yet contain precision and bias statement, will become less important and thus a conclusive and important test method for the determination of germ proofness characteristics of porous materials will be challenged.

Within the framework of the planned round robin test the necessary validation data shall be ascertained for the DIN 58953-6.

Planned carrying out of the round robin test:

Sample material:

The round robin test shall contain both test procedures (germ proofness under humidity according to subclause 3 and germ proofness with air permeance according to subclause 4). It is considered to examine three samples with different germ proofness levels of two materials (paper and nonwoven).

Costs:

The costs for the participation in the planned interlaboratory test are probably € 100.00 for each laboratory.

Time period:

The interlaboratory test will presumably be carried out in the middle of 2011 after completion of the preparations which are being carried out at the moment.

Application:

In case of interest please contact:
ISEGA Forschungs- und Untersuchungsgesellschaft mbH
Mrs. Dr. Julia Riedlinger
Zeppelinstraße 3-5
63741 Aschaffenburg / Germany
Tel.: +49 6021 49 89 0
Fax.:+49 6021 49 89 30
Email: info@iseqa.de