confirmation

greiner BIO-ONE

Product performance for Virus Stabilization Tubes

We at Greiner BIO-ONE hereby inform,

regarding the product performance of following VACUETTE® Products

456161 / 456162 – Virus Stabilization Tube

In course of internal performance testing (STA-20GBO184), the impact of transport to the functionality of above-mentioned tubes was evaluated. Transport stability studies investigate the tolerance of a medical device to the kinds of environmental and mechanical conditions to which it is likely to be subjected in the time between shipping from the manufacturer to its final user.

The transport validation was executed according to ASTM D4169-16, Distribution Cycle 13 and in accordance with ASTM D4332-14. The test schedule, which was conducted with the tubes in their standard shipping box, combined mechanical stress like compression, free fall, low pressure, vibration and concentrated impact as well as climatic stress including a temperature range of -30°C to +40°C (-22°F to 104°F) for 72h and at 60°C (140°F) for 6h. The relative humidity was thereby varied from 15% to 90%.

The evaluation of product parameters such as cap torque, additive properties and leakage testing of transport stressed samples leads to the confirmation, that above-mentioned tubes withstand the harsh conditions (as defined in ASTM D4169 and ASTM D4332) during transport to the customers without any deterioration of their performance.

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Date & Signature
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