

healthmark INDUSTRIES CO. health care products

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Healthmark Offers Artificial Test Soil (ATS) Developed from Scientific Research

Fraser, MI Dec. 30, 2011- Healthmark offers Artificial Test Soil to comply with AAMI, the FDA, CDC, CEN, Health Canada, CSA, and other regulatory agencies around the globe: Validation of medical device cleaning, disinfection and sterilization should be done with test soils that are modeled on the residuals the medical device is likely to be contaminated with during actual clinical use.

The ATS formulation is based upon research data representing the "worst case" soil level from patient-used medical devices, and therefore represents a standardized soil formulation that is applicable to simulated-use testing of a wide range of medical device.

ATS is composed of known quantities of protein, carbohydrate and hemoglobin, in proportion to the worst-case levels found in patient-used surgical instruments. Further ATS can be inoculated with microbiological markers for challenging sterilization/disinfection. FDA and AAMI guidelines direct medical device manufacturers (MDM's) to use "worst case conditions" in their simulated-use testing. In addition, MDM's are directed to use an organic challenge that represents the types of soil to which the device will be exposed during clinical use. Guidance documents also recommend "... that the bioburden challenge (organic and microbial) to the cleaning and or disinfection process of the washer and washer disinfectors be determined from clinically used devices (FDA Guidance Document for Washer Disinfectors, 2002)."

About Healthmark Industries Co., Inc.

Since 1969, Healthmark Industries Company, Inc. has developed and marketed innovative solutions to aid healthcare facilities in their delivery of surgical instruments and other life saving medical devices to patients. Healthmark Industries mission is to

continue to innovate, continue to support and continue to serve the healthcare provider industry and support services that make it possible to deliver quality healthcare. Visit www.hmark.com for more information.