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Sterilization of Aquabiliti Single-Use System Products – Customer Notice

Aquabiliti partnered with a contract laboratory to determine a validated method for a minimum sterilization dose of 25kGy for Aquabiliti Single-Use System Products. The sterilization validation method is product bioburden based and is compliant with ANSI/AAMI/ISO 11137-1, Sterilization of health care products – Radiation – Part 1: Requirements for the development validation and routine control of sterilization process for medical devices as well as ANSI/AAMI/ISO 11137-2, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose. In addition to validating 25kGy as the minimum sterilization dose, the study was done to validate the holding time of the Single-Use System Products. The validation work is captured under YRK-QA-VAL-0121, Minimum Sterilization Dose Validation VDmax^{25}.

The test evaluated a "Monster Bag" which is representative of the entire family of products encompassed in Aquabiliti's Single-Use System Products. The "Monster Bag" was utilized as the master challenge device from a bioburden perspective because it poses the greatest challenge to the sterilization process based on the materials used, and the design and complexity of the bag. The study utilized three (3) independent manufacturing lots to determine the average bioburden of the product family. The methodology for establishing the bioburden's resistance verification dose was done in compliance with ANSI/AAMI/ISO 11137-1 and 11137-2 for validating a minimum 25kGy radiation sterilization dose using the VDmax^{25} methodology.

The Acceptance Criteria for establishing a minimum sterilization dose of 25kGy were:

- The average bioburden estimate achieved for the "Monster Bag" would be $\leq$ 1000 CFU for each of the three (3) lots tested. **The results were acceptable. See the data below.**
- The delivered verification dose could not deviate more than $\pm$10% of the calculated sublethal dose. **The results were acceptable. See the data below.**
- No more than one (1) test of sterility sample from the ten (10) samples tested could be positive for microbial growth in order to substantiate the minimum 25kGy dose. **The results were acceptable. See the data below.**

Results:

Result	**BAG-0200-02, 200L "Monster Bag"**
Bioburden Estimate	12.8 CFU (Average for 3 lots), <14.4 CFU (Maximum Read)
Verification Dose (as determined by ANSI/AAMI/ISO 11137-2 Table 9,)	7.4kGy $\pm$ 0.7kGy
Delivered Dose	7.02 – 7.71kGy
Sterility Test	10 Negative for Growth
Validated Pre-Sterilization Hold Time	89 Days

The results of the testing for the “Monster Bag”, which is the representative challenge device that encompasses all Aquabiliti Single-Use System Products passed all acceptance criteria for the Method VDmax^{25} sterilization validation. Based on these results, all Aquabiliti Single-Use System Products can be irradiated with a minimum dose of 25kGy to achieve a Sterility Assurance Level (SAL) of 10^{-6}. In addition to the validation work that has been completed to establish the minimum sterilization dose. Aquabiliti conducts dose audits to ensure that the established range is still effective for the Single-Use System Products.

Please see the list of reference documents supporting the above data:

ANSI/AAMI/ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for the development validation and routine control of sterilization process for medical devices
ANSI/AAMI/ISO 11137-2	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose BIOX24022900
YRK-QA-VAL-0121	Minimum Sterilization Dose Validation VDmax^{25}

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