

March 11, 2025

To Whom it May Concern,

Thank you for being a valued Aquability customer and for your interest in our Quality Systems. We recognize the vital role that Supplier Qualification Programs play in your organization and understand how critical these activities are for controlling and effectively managing the supply chain in the regulated industries.

At Aquability, we are committed to supporting the quality needs of our customers. To ensure a timely and efficient response to your requests, we have prepared a comprehensive document outlining our Company and Quality Systems.

We trust this information will meet your Supplier Qualification requirements. Please do not hesitate to reach out if you need additional details or assistance.

Thank you for choosing Aquability. We value our partnership and look forward to continuing to support your business needs.

This report contains information on the following categories.

- Company Information
- Quality Management Systems
- Quality Management Processes and Programs
- Employee Effectiveness
- Material Control
- Production and Process Control
- Quality Control/Quality Assurance
- Equipment, Facilities, and Utilities
- Labeling
- Product Knowledge

Attachments also include

- Aquability Organizational Chart
- Certificate of Compliance and Label Samples
- ISO 13485 Certificates

Aquability attests the following information is factual and that the persons providing this information are authorized to do so. If you need more specific information that is not provided here, please contact us.

Thank you for your cooperation,



Craig Collins  
Quality and Sterility Assurance Manager  
Aquability

**Table 1: Company Information**

<b>Company Name</b>	Aquability
<b>Company Address</b>	5209 Linbar Drive Suite 640 Nashville, TN 37211
<b>Company Country</b>	United States
<b>Company Telephone Number</b>	615-833-2633
<b>Company Fax Number</b>	615-425-2772
<b>Type of Business</b>	Medical Device Manufacturing
<b>Year Facility Established</b>	2005
<b>Do you operate more than one site?</b>	No
<b>Parent Company Name</b>	Aquability Holdings LLC
<b>Contact Information</b>	customercare@aquability.com
<b>Number of Quality Employees</b>	4
<b>Number of Production/Operations Employees</b>	21
<b>Organizational Structure</b>	Please see Attachment 1
<b>Product Types.</b>	Sterile Pre-Filled 0.9% Sodium Chloride Flush Syringes
<b>Would you allow an Audit from our Company?</b>	Yes
<b>Would the visiting Customer need to sign an NDA in order to visit site?</b>	Yes
<b>Primary markets served.</b>	Health Care Institutions, Facilities and Providers

**Table 2: Quality Management Systems**

<p><b>Is the Site Certified – ISO 13485?</b>  Registrar for ISO 13485: BSI Group</p>	<table border="1"> <thead> <tr> <th>Standard</th> <th>Certificate #</th> <th>Expiry Date</th> </tr> </thead> <tbody> <tr> <td>ISO 13485:2016</td> <td>FM 671801</td> <td>2028-02-05</td> </tr> </tbody> </table>	Standard	Certificate #	Expiry Date	ISO 13485:2016	FM 671801	2028-02-05
Standard	Certificate #	Expiry Date					
ISO 13485:2016	FM 671801	2028-02-05					
<p><b>Is the Manufacturing Facility in compliance with current Good Manufacturing Practices?</b></p>	<p>Yes</p>						
<p><b>Is the Site Accredited, Certified or Registered with a Regulatory Agency?</b></p>	<p>Yes</p>						
<p><b>Is the site FDA Registered/Registration Number?</b></p>	<table border="1"> <thead> <tr> <th>Registration #</th> <th>Last Registration Date</th> <th>Last Inspection</th> </tr> </thead> <tbody> <tr> <td>1057300</td> <td>2025</td> <td>2022</td> </tr> </tbody> </table>	Registration #	Last Registration Date	Last Inspection	1057300	2025	2022
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1057300	2025	2022					
<p><b>Any aspects of the Manufacturing Process Subcontracted?</b></p>	<p>Yes, Sterilization</p>						
<p><b>Quality and/or Technical Agreements with subcontractors including intellectual property protection?</b></p>	<p>Yes</p>						

**Table 3: Quality Management Processes and Programs**

<p><b>Do you have a Quality Policy and/or Manual? If yes, briefly describe.</b></p>	<p>Yes, we do have a Quality Policy and a Quality Manual, and they are compliant to ISO 13485:2016</p>
<p><b>Other Processes and Programs that are in place include:</b></p>	<ul style="list-style-type: none"> <li>• Internal Audit Program</li> <li>• Supplier Qualification &amp; Audit Program</li> <li>• Training Program</li> <li>• Change Control</li> <li>• CAPA System</li> <li>• Document Control</li> <li>• Non-Conforming Product and Process Program</li> <li>• Pest Control Program</li> <li>• Preventive Maintenance Program</li> <li>• Calibration Program</li> <li>• Out of Specification and Retest Procedures</li> <li>• Warehouse System</li> <li>• Incoming Material Inspection</li> <li>• Product Identification and Traceability</li> <li>• Deviation &amp; Investigation Reporting</li> <li>• Non-Conformance Reporting</li> <li>• Validation Program or Process</li> <li>• Environmental Monitoring program</li> <li>• Labelling of Intermediate and/or Final Products</li> <li>• Storage of Intermediate and Final Products</li> <li>• Material Receiving and Incoming Inspections</li> <li>• Inventory Management</li> </ul>

**Table 4: Employee Effectiveness**

<p><b>Do you have Training Plans for all employees?</b></p>	<p>Yes</p>
<p><b>What types of Training do you use?</b></p>	<p>Various methods are used, including On-the-Job, Class Room, Web Training. For specific technical needs, external training may be used.</p>
<p><b>Do you maintain Training Records?</b></p>	<p>Yes</p>
<p><b>Are your Training Records up to date?</b></p>	<p>Yes</p>
<p><b>Competence Assessment Use?</b></p>	<p>Yes</p>
<p><b>Are Job Descriptions available?</b></p>	<p>Yes</p>
<p><b>Is there a GMP Training Program?</b></p>	<p>Yes</p>

**Table 5: Material Control**

<b>Do you have an Approved Supplier List?</b>	Yes
<b>Do you have a process to qualify new or existing Critical Suppliers?</b>	Yes
<b>Do you have Purchasing Procedures that require the ordering of critical materials from approved Suppliers.</b>	Yes
<b>Is there a Dedicated Receiving Area for Raw Materials.</b>	Yes
<b>Do you have Supplier Change Notification Agreements? If yes, please describe.</b>	Yes. We do have processes in place to be notified by our Suppliers of any changes that effect Form, Fit, Function, or Country of Origin of the Product
<b>Do you have written specs for all Incoming Raw Materials?</b>	Yes
<b>Do you evaluate received Material for verification?</b>	Yes, as defined by specification and risk level
<b>Do you have procedures and keep Records of the control of Raw Materials?</b>	Yes
<b>Do you have Raw Material Lot Traceability Process?</b>	Yes
<b>Can you trace Raw Material Lot Numbers to Aquabiliti Lot Numbers?</b>	Yes
<b>Can you trace Raw Material Lot to Supplier Lot Number?</b>	Yes

**Table 6: Production and Process Control**

<b>Do you have a Device History Record for each Lot?</b>	Yes
<b>Do In-Process Product containers bear ID or Lot Labels? If yes, list information on Label?</b>	Yes. Part #, Lot # and/or date are minimum requirements.
<b>Are procedures in place to prevent cross contamination? If yes, please describe.</b>	Yes. Line clearance procedures exist to prevent cross-contamination.
<b>Are Line Clearances done between Products?</b>	Yes
<b>Are cleaning and sterilization processes validated?</b>	Yes
<b>Are Production Operations planned and performed under controlled conditions to ensure Product conforms to its specifications?</b>	Yes
<b>Do you have defined procedures for testing and/or inspection done during and between Manufacturing Processes or stages?</b>	Yes

**Table 6: Production and Process Control (continuation)**

<b>Do you have defined procedures for testing and/or inspection done on Finished Goods?</b>	Yes
<b>Do you have a defined area for storage of Released Materials?</b>	Yes
<b>Do you have a defined area for holding for Non-Conforming, Quarantined or Rejected Material?</b>	Yes
<b>Do you have a Rework Policy?</b>	Yes. All Rework activity must be properly documented, approved, and verified.
<b>Are Manufacturing Procedures and Processes Validated?</b>	Yes, per Validation processes.
<b>Do Batch Records identify Equipment used?</b>	Yes
<b>Do you manufacture Product with dedicated Equipment?</b>	No, however every Equipment is Validated for the Product to be manufactured according with the Validation Process.

**Table 7: Quality Control**

<b>Do you have a Quality Control (QC) group and is it independent of Production?</b>	Yes
<b>Do you have defined procedures for all performed tests (including Laboratory Tests)?</b>	Yes
<b>Do you have Record Retention on all samples submitted to the Lab? If yes, how long?</b>	Yes
<b>Does your QC Lab Record have the Date Sample Received, Test Date, ID/Product Code, and Test Results?</b>	Yes
<b>Are Analytical Methods Validated?</b>	Yes
<b>Does the Lab have a procedure for handling Out-of-Specification results?</b>	Yes
<b>Is every Batch produced evaluated for conformance?</b>	All Products require In-Process Testing/Inspection. Functional testing of Finished Goods is performed per validated Sampling Strategy.
<b>Do you perform all your QC Testing in House?</b>	No. Testing occurs both In-House and is subcontracted to approved Laboratories, depending on the product and the required tests.

**Table 8: Quality Assurance**

<b>Do you have a Quality Assurance (QA) group and is it independent of Production?</b>	Yes
<b>Do you have procedures covering the Release or Rejection of Material (both Raw Materials and Finished Goods)?</b>	Yes
<b>Is there a Device History Record review for Batch/Lot Release?</b>	Yes
<b>Does the QA Group have responsibility to review the Documentation (Batch/Lot Release Records) for release or rejection of Finished Product?</b>	Yes
<b>Do you supply any Certificate with each Lot (Certificate of Compliance - CoC, or Certificate of Analysis - CoA) where applicable?</b>	Yes  CoA (Product Released Lots) located at: <a href="https://www.aquability.com/resource-library.html">https://www.aquability.com/resource-library.html</a>
<b>Are all Deviations and Non-Conformances investigated, documented and filed?</b>	Yes
<b>Is there a Customer Complaints Process in place?</b>	Yes
<b>Is there a Corrections and Recall plan in place?</b>	Yes
<b>Would you notify Customer in writing prior to implementing a major change to the Product?</b>	Yes
<b>Does Leadership hold Periodic Reviews of the Quality Systems - Confirm Conformance and Identify Improvements (Audit Results, Complaints, Feedback, CAPA, etc.)?</b>	Yes, as part of the Management Review process.
<b>Do you conduct regular Internal Audits?</b>	Yes

**Table 9: Equipment, Facilities and Utilities**

<b>Are the Cleanrooms subject to Microbiological Monitoring?</b>	Yes
<b>Do you have Maintenance and Preventative Maintenance plans for all pieces of Equipment including Measurement Equipment?</b>	Yes
<b>Do you have Maintenance and Calibration Procedures for critical Equipment including Measurement Equipment?</b>	Yes
<b>Are Calibrations traceable to (national) standards? If yes, which standards.</b>	Yes (NIST, OEM or other standards that may be applicable)
<b>Are Calibration Records controlled and retained?</b>	Yes
<b>Do you have a policy or procedure for validation of Testing and Measuring Equipment?</b>	Yes, per specification.
<b>Do you have a Pest Control program?</b>	Yes
<b>Are Computer Systems validated? And comply with 21 CFR part 11?</b>	Yes
<b>Is there a backup process for Electronic Records?</b>	Yes
<b>Are Computer Records secured against unauthorized alterations?</b>	Yes
<b>Is there a Backup Generator?</b>	Critical systems have backup generators.
<b>Temperatures Controlled/Monitored?</b>	Yes

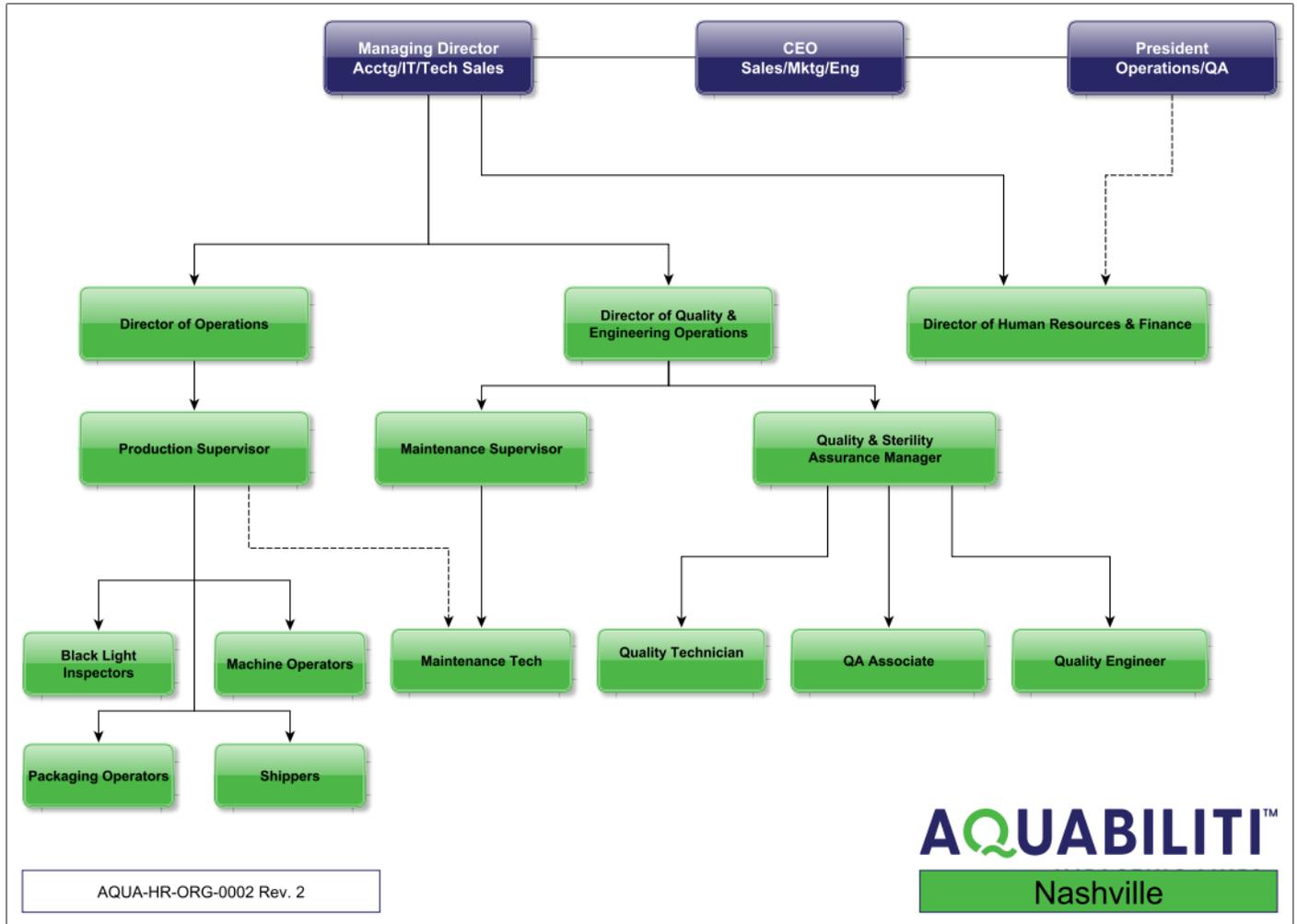
**Table 10: Labeling**

<b>Is each Container (shelf pack or case) labeled with the Batch or Lot Number? If yes, list information on Label?</b>	Yes. Label information is defined by Product Code and Lot Number.
<b>Does each Container (shelf pack or case) on pallet have Batch or Lot Number visible?</b>	Yes
<b>Do you have Written Procedures for the control and issuance of Labelling Materials?</b>	Yes
<b>Are Labels stored in a secure area?</b>	Labels are usually printed as per demand as part of the Manufacturing System. In case Labels are preprinted they are stored in a secure area.

**Table 11: Product Knowledge**

<b>Are Records maintained which define inputs (functional and performance requirements; applicable statutory, regulatory and safety requirements; previous Design Information) relating to the Product Requirements?</b>	Yes
<b>Do you have Expiration Dates for Materials, Components and Products?</b>	Yes, where applicable.
<b>Are Storage Conditions defined to avoid Degradation Contamination and Cross Contamination?</b>	Yes
<b>Are proper Handling Procedures defined to avoid Degradation, Contamination, and Cross Contamination?</b>	Yes
<b>Are any Products partially or fully of Animal Origin? If yes, please describe.</b>	No
<b>Are products manufactured using natural rubber latex?</b>	No
<b>Do you have Stability Testing program?</b>	Yes
<b>Are you able to provide Safety Data Sheets?</b>	Yes

**Attachment 1: Organizational Chart**



**Attachment 2: CoA and Label Example**


NSH1-QA-WIF-0164 Rev.1

### Certificate of Compliance

Pre-Filled, Flush Syringes with 0.9% Sodium Chloride (Saline)

Customer PO	123456789
Lot Number	<b>KH0XXXX</b>
Component Specification	RM0738827 REV 1
Aquabiliti Part Number	2S0706
Date of Manufacture	19-Dec-2024
Expiration Date	<b>19-Dec-2027</b>
Quantity (Eaches)	150,000

This product conforms to all Aquabiliti specifications for commercial release.

This product has been manufactured and tested in accordance with 21 CFR Part 820.  
This product has been manufactured in accordance with Sodium Chloride Injection, USP current revision.  
This product was tested in accordance to USP <85> and determined to be free of endotoxin (pyrogen) per required limits.  
This product has been sterilized in accordance with the requirements of ISO 11137.

The undersigned certifies this to be a true representation of the results.

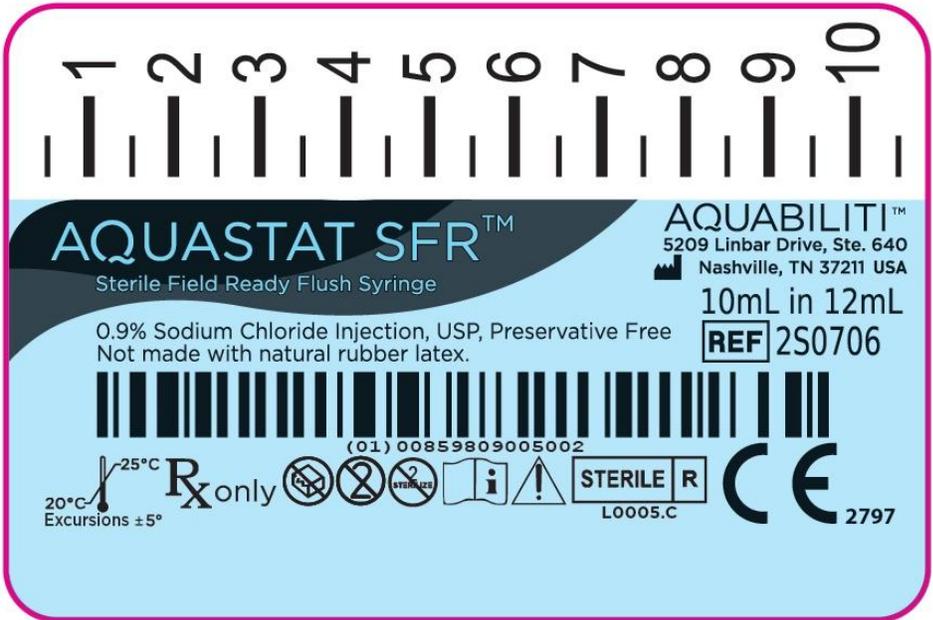
Created By:

\_\_\_\_\_  
Craig Collins  
Supervisor, Quality and Regulatory Affairs

Approved By:

\_\_\_\_\_  
Jag Davis  
Quality & Regulatory Affairs

5209 Linbar Drive, Suite



**Attachment 3: ISO Certificate**




**Certificate of Registration**

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

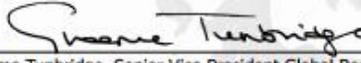
**MRP LLC**  
**dba Aquabiliti**  
 5209 Linbar Drive  
 Suite 640  
 Nashville  
 Tennessee  
 37211  
 USA

Holds Certificate Number: **FM 671801**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Manufacture, and Distribution of Sterile Saline Flush Syringes.

For and on behalf of BSI:

  
 Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-02-06  
Latest Revision Date: 2024-10-30

Effective Date: 2025-02-06  
Expiry Date: 2028-02-05




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