Nordson MEDICAL

Shelf-Life Testing

PROVIDING THE SOLUTIONS THAT BRING INNOVATIONS TO LIFE

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Providing the Solutions that bring Innovations to Life

Nordson MEDICAL is committed to excellence:

As the global expert in the design, development, and manufacturing of complex biopharmaceutical medical devices and component technologies, Nordson MEDICAL offers innovative tools, technologies and solutions that can help your team bring critical technologies and complex devices to market faster and more cost-effectively.

Quality is paramount in everything we do because our components and finished devices are used to save or enhance patients' lives every day. We have developed a culture of continuous improvement and a single global quality system to ensure reliable, consistent product performance. Our commitment to excellence is at the heart of our interactions with customers, suppliers, and coworkers.

That commitment to excellence continues with our shelf-life testing program designed to meet the American Society for Testing Materials (ASTM) F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices and provide our customers with solutions that can help bring critical technologies and complex devices to market faster and more cost-effectively and deliver on our promise to ensure reliable and consistent quality with all our products.

We design and manufacture components and finished devices that have a direct and positive impact on the lives of countless patients around the world. From our line workers to our design engineers, we hold ourselves to the highest standards of quality.

Why is shelf-life testing important?:

As an engineer determining the shelf life of an assembly, it is important to understand the underlying principles that each component brings to that assembly. Have the individual components been tested after undergoing sterilization treatment and then subjected to accelerated aging to reflect how the product will be used in normal production? Was the validation testing realistic, and does it reflect the type of usage each component will be exposed to in the application? Was the aging timeframe beyond the expectation normally seen in assemblies used to produce vaccines or therapies? If the answers to all these questions are yes, then engineers should feel that a solid risk-based approach can be used to determine the shelf life for the assembly being evaluated. Ranking each component's validated shelf-life expectancy from shortest to longest, the assembly shelf life should be equal to the shortest number. For example, if the shortest number for a single component is rated at two years, then the manufacturer should expect to put the assembly into service less than two years minus the normal production processing time for that drug product.

This level of understanding is important to make informed decisions on when to put assemblies into service or to make safe decisions on when to scrap assemblies that have approached the end of their shelf life.

Our testing structure:

At Nordson MEDICAL, our goal is to establish a realistic shelf-life claim as we work with assemblers and system integrators to establish a shelf-life number - or number of years a product will maintain its performance integrity - for complex multi-product assemblies. To accomplish this goal, the Quality Assurance team at Nordson MEDICAL, in partnership with our team of engineers and product managers, conducts a battery of tests based upon accelerated aging, post- sterilization tests.

To meet the ASTM F1980-16 standards, our Quality Assurance team at Nordson MEDICAL has taken on the task of testing entire product families with the goal of meeting a 4-year shelf-life claim. These tests are conducted using accelerated aging based on the standards provided by the ASTM and gamma sterilization of 50 KiloGray (kGy) to expedite accurate testing results.

These product families are tested before and after accelerated aging and gamma exposure to verify fit and functionality. Components such as luer fittings are tested for leaks, unscrewing, overriding, and axial pull. Products such as quick connects are tested for barb terminations and O-ring conditioning. All products undergo a drop test of 36 inches, or 91.44 centimeters, while others undergo logical tests to prove suitability for use.

"At Nordson MEDICAL, we continue to work on behalf of our customers to help them mitigate risk, ease the burden of validation and get to market quicker."

-JORDAN BERKEL

Product Specialist

Testing influencers:

As your single-source partner, our team of product managers are available to assist you in identifying how to apply our shelf life data for your specific production assembly. We will help guide you to determine which influencers - such as average age of your existing inventory, average time it takes to flow from our components to drug production, or product range – will provide the most accurate shelf-life test results for the overall assembly.

Product Families Tested	Test Article Used
Tube to Tube Fittings	N670-J1A and N690-6005
Sanitary Fittings	SFMX680-6005 and SFMX655-J1A
RQ Series Quick Connects	RQCM/F670-6005 and RQCM/F670-9024
Luers	M/FTLL240-9002 and M/FTLL240-6005
PharmaLok™	CPAX150-U75
Bag Ports	SFBP680-VP1 and SFBP6100-CM056
CylindraFlow™	FMD5P670-001
Spaulding AQC	SDAVF670NPS-001 and SDAVM670NPS-001

Conclusion:

This shelf-life testing effort, coordinated by the Quality Assurance team at Nordson MEDICAL, represents a commitment to quality design, materials, and compliance to ATSM F1980-16 standards. As a global leader in the biopharmaceutical industry, our goal is to continuously improve in all phases of manufacturing. By providing shelf-life testing data that meets the rigorous standards of the ATSM, we are strengthening the supply chain and our role as leaders in this thriving industry.

As we work through the process of testing product families, Nordson MEDICAL will continue to partner with companies at any point in the product lifecycle – working with component manufacturers, assemblers, and system integrators to establish a shelf-life number for complex multi-product assemblies.

Contact your Nordson MEDICAL sales representative for more information or visit nordsonmedical.com

About Nordson MEDICAL

Nordson MEDICAL is a global expert in the design, development, and manufacturing of complex medical devices and component technologies. We serve interventional, surgical, and specialized markets with technologies that save or enhance lives. As an integrated, single-source partner, we enable our customers to save costs and speed time to market.

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