

MANUFACTURER'S NOTIFICATION

Expiration Dates Validation and Extension – Details about Qualitix® sterile pipette tips

Expiration Date Extension

Qualitix® sterile pipette tips are FDA-compliant Sterile products (21 CFR 211) manufactured according to GMP and CE-IVDD requirements. In compliance with these regulations, the shelf life of Qualitix® sterile pipette tips is currently validated at 3 years (36 months) from the date of manufacture. Qualitix® products may be used in all applications and environments without restriction (FDA regulations 21 CFR 820).

Shelf-life expiration periods are set to ensure that all items delivered to customers and used before the expiration date meet all claims for Sterility and performance claims. In early 2022, multiple long-term studies were initiated to determine whether Socorex can increase the length of time during which Qualitix® sterile pipette tips products may be used safely. These extensive studies were completed in May 2023 (as required by FDA [21 CFR 211.166]). Results indicated that Socorex is able to increase the shelf life of Sterile products from 3 years to 5 years (60 months) from the date of manufacture.

Shelf-life modifications will be implemented as new products are produced. Products already labeled and in stock cannot be changed. Products already in the supply chain (shipped or in stock) satisfy all certifications and claims of the newly established shelf life and may be used past their expiration dates. Socorex will provide certificates of expiry extension upon request for any items that are not expired according to the new classifications.

FREQUENTLY ASKED QUESTIONS:

How long are the new expiration periods?

Sterile products now expire 60 months after date of manufacture.

Can I use the products I have that are expired safely?

Probably. Products in the supply chain with an expiration date beginning in June 2023 may be used safely through the periods noted above.

How do I know what the new expiration date is on an item I have?

Items with an expiration date until June 2023 (6-2023) that are marked Sterile will now expire in June 2025. Current indication of the expiry date refers to a shelf life of 36 months. The extension of the shelf life gives an additional 24 months (36 + 24 = 60 months) time to use the Qualitix® sterile pipette tips while keeping the same guarantee of sterility.

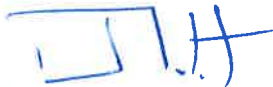
Can I obtain documentation of this change?

A certificate is available for any items with expiration dates beginning in June 2023 that you would like to use past that marked expiration date.

Requesting a Certificate

Contact your distributor with the product number and lot number to obtain the new certificate.

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Ecublens, June 27th, 2023