

Sterilization Certificate – Qualitix® reagent reservoirs

Socorex® certifies that the 8 and 12 channels Qualitix® reagent reservoirs, intended for use in the laboratory field, are sterilized. SAL for sterilized products is ensured by validation of the irradiation process according to the procedure below.

Sterility SAL (sterility assurance level): 10^{-6}

Sterilization ref:

Treatment according to the requirements of ISO 9001, ISO 13485, ISO 11137 - Sterilization of Healthcare Products, and 21CFR Part 820 (FDA c GMP)
Synergy Health validation report SOP - BL11XAe0 in order to ensure the above mentioned SAL

Method:

Irradiation unit : X-Ray
Specified min dose : 25 kGy
Specified max dose : 40 kGy
Dosimeter type : Alanine

Release method / sterility validation:

ISO 11137 Sterilization of Health Care Products – Validated product treatments
According to dosimeter measurements, calculated Min. and Max. doses must be included within specified dose range (kGy)

Model	Cat. No.	Lot No.
Process run date	Doses (kGy)	Expiry



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Ecublens,

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