

Sterility Assurance Level (SAL) Declaration

To Whom It May Concern

The sterilization process applied by HTL-Strefa S.A. to its medical devices is irradiation – as per the requirements of ISO 11137-2 and ISO/TS 13004. The component of safety lancets subject to irradiation is the needle carrier for which the Sterility Assurance Level (SAL) = 10^{-6} is required.

The sterilization dose determination, its validation and revalidation is performed based on ISO 11137-2 and ISO/TS 13004. The established SAL for all sterile devices of HTL is $SAL10^{-6}$. The range of irradiation dose is 17.5kGy – 40kGy.

Sincerely,

Izabela Banaś



Senior RA Specialist