CERTIFICATE OF COMPLIANCE

RATIOLAB is certified according to **ISO 9001 : 2015, ISO 13485 : 2016**

RATIOLAB certifies that following products were controlled and comply with their specifications.

Sterilization : The product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, „Sterilization of health care products-Radiation“. Products meet a minimum Sterility Assurance Level (SAL) of 10^{-3}.

Pyrogens : Products have been tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>, “Bacterial Endotoxins Test”. The acceptance level for product ≤ 0.125 EU/ml or ≤ 5 EU / device.

RNase / DNase Testing : Products have been tested by nuclease assay method and found to be free of detectable DNase/ RNase contamination. The assay detection limit is 10^{-7} Kunitz units/ uL for DNase and 10^{-9} Kunitz units/ uL for RNase.

USP Class VI Testing : All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter <87>, “Biological Reactivity Tests, in Vitro” and Chapter <88>, “Biological Reactivity Tests, in vivo”

BSE/ TSE : Product complies with the latest revision of EMA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/ 410/01.

Accuracy : Serological pipets are accurate to +/- 2% at full volume in compliance with ASTM E934, “Standard Specification for Serological Pipet, Disposable Plastic” and ISO 12771, “Plastics laboratory ware – Disposable serological pipettes”.

This(ese) manufacturing lot(s) has(ve) been sampled and tested in accordance with Standard Operating Procedures and has been released by Quality Assurance for the following characteristics :

Test / Procedure :	Results
Visual Attributes :	Passed
Volumetric Accuracy :	Passed
Packaging :	Passed

Catalogue #: **3125011**

Serial # : **31250114266077**

Product description: **Serological pipets 25 ml, Sterilized, single wrapped**

Condition : **EXPIRY DATE: 09.2027**

Ratiolab GmbH
D-63303 Dreieich, 07.03.2025
Quality Control Department
This document was sent online and is valid without signature

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