Certificate of Conformity

VWR Catalogue Number	See List
Description	Aspirating pipettes, Sterile
Country of Origin	Manufactured in China
Date of Issue (yyyy-mm-dd)	2025-09-01

Catalogue Number	Capacity [mL]
612-5883	1
612-5884	2
612-5885	5
612-5886	10
612-5887	25

Quality System Compliance

This certificate confirms that the product has been sourced from a supplier or manufacturer who has declared their Quality Management System (QMS) complies with **ISO 13485:2016.**

QC Testing

Representative products samples are collected and inspected in accordance with current applicable QC requirements.

Product Specifications

The product is Class I category device as defined by FDA in 21CFR Parts 862-892.

Material 100% High Clarity Polystyrene.
Use at -20 to + 50°C.

Sterilization Product labeled as sterile is EB (Electron Beam) irradiated and dose released upon ISO11137 recommended practices in effect at the time of validation. Products labeled sterile meets a minimum requirement of 10^{-6} SAL with a specified dose range of 22-40 kGy.

Nitrosamine This product does not contain nitrosamine.

ATP Assay	Not Applicable.
DNase & RNase Free	This product is free of any detectable DNase/RNase contamination.
BSE/TSE	No use of any raw material produced from or substances derived from animal origin. The manufacturing process of the product does not use any ingredient of animal origin and no material derived from or exposed to animals affected by or under quarantine for transmitting Animal Bovine Spongiform Encephalopathy/Spongiform Encephalopathy (BSE)/(TSE). With reference to guideline EMEA/410/01.rev3
Cytotoxicity	Testing is conducted to quality all material resins using ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.
Non-Pyrogenic Statement	The acceptance level for product is 0.5 EU/mL or less than 20 EU/device LAL Gel Clot Method. (Tested according to Chinese Pharmacopoeia 2015, General Chapter <1143>, equivalent to USP <85>).
Latex Statement	Not Applicable.
BPA Statement	Bisphenols are not used in the manufacture of the raw material and are not expected to be present.
DEHP Statement	Not Applicable.
RoHS	No substances (Lead, Cadmium, Mercury, Hexavalent Chromium (Cr6+), Poly Brominated Biphenyls (PBB), Poly Brominated Diphenyl ethers (PBDE), Bis(2-Ethyhexyl) Phthalate (DEHP), Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP), Diisobutyl Phthalate (DIBP)) are used in manufacturing the raw materials and final product. No routinely analyse is performed).
REACH Statement	Not Applicable.
Storage Conditions	Room Temperature.
Shelf Life	4 years.

Disclaimer: VWR's Quality Management System (QMS) is ISO 9001:2015 certified as a wholesale distributor of finished products, ensuring effective oversight of finished product handling, traceability, and distribution processes. VWR is not a manufacture and does not engage in manufacturing, co-manufacturing or processing activities such as design, packaging, labeling, testing or quality release. Consequently, the supplier or manufacturer's QMS certification may differ from VWR's.

VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. This product is intended for research use only. It is not for use in diagnostic procedures, therapeutic applications, or any human or clinical use.

This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	1.1	Created General CoQ using new layout	10-2021
2	1.2	Added Nitrosamine Statement	10-2021
3	2.0	Modified Sterilization method, Quality system compliance and disclaimer	08-2025