

Certificate of Conformity

Catalogue Number	See list
Description	Dispenser tips, classic, sterile
Country of Origin	Manufactured in Germany
Date of Issue (yyyy-mm-dd)	2023-01-12

Catalogue Number	Item Description	Volume [mL]	UOM [pcs]
613-1008	Dispenser tips classic sterile	0.05	100
613-1009	Dispenser tips classic sterile	0.5	100
613-1010	Dispenser tips classic sterile	1.25	100
613-1011	Dispenser tips classic sterile	2.5	100
613-1012	Dispenser tips classic sterile	5.0	100
613-1013	Dispenser tips classic sterile	12.5	100
613-1014	Dispenser tips classic sterile	25.0	25
613-1015	Dispenser tips classic sterile	50.0	25

Quality System Compliance

Products are manufactured in **ISO 13485:2016** and **ISO 9001:2015** certified plant. Products are inspected and controlled in accordance with the current applicable product specification.

QC Testing

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

Product Specifications

Material

Tube: Polypropylene
Plunger 0.05 ml tip: high density polyethylene + pin (= stainless steel)
Plunger 0.5 ml – 50.0 ml: high density polyethylene (HDPE).

Sterilization

Products are EB (Electron Beam) irradiation and dose released upon ISO 11137-2:2013.

ATP Assay	Tested with detection level < 1* 10 ⁻¹² mmol.
PCR Inhibitor	Product yield equivalent to control <10 amplifiable targets.
DNase & RNase free	Tested with detection level < 1* 10 ⁻⁶ KunitzU (DNase) and < 1* 10 ⁻⁹ KunitzU (RNase)
Nucleic Acid Free	Human DNA free, tested with detection level < 1 pg.
Manufacturing Environment	Dispenser tips are manufactured under controlled conditions.
BSE/TSE	Tallow derived additives may be used in the manufacture of the raw materials. These tallow derived additives are in compliance with the guidance EMA/410/01 Rev. 3 – July 1, 2011 "Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products", adopted by the European Commission and published in the Official Journal of the European Union March 5, 2011 (2011/C 73/01). To the best of our knowledge, these treatments ensure inactivation of any agents present in the tallow derivatives to be used in plastics materials. We therefore can state that this grade is considered safe to use with respect to BSE and TSE transmissions.
Cytotoxicity	Not applicable.
Non-Pyrogenic Statement	Endotoxin free, tested with detection level < 0.02 EU/Unit.
Latex Statement	Not applicable.
BPA Statement	Not applicable.
DEHP Statement	Not applicable.
RoHS	The raw materials used are compliant with the currently valid directive 2011/65/EU and 2002/95/EG (RoHS).
REACH Statement	The product does not contain any "SVHC" ingredients, in accordance with the currently valid regulation (EC) No 1907/2006 on REACH.
Storage Conditions	Keep dry and away from sunlight.
Shelf Life	5 years.

Disclaimer: VWR states that this declaration will not discharge the user from their obligation to ensure the product is suitable for the intended use. The purpose of the product is for use in laboratory only.
This document has been produced electronically and is valid without a signature.

Version History

Sl.no	Version number	Description	Month & Year
1	4.1	Created General CoQ using new layout	10-2022
2	4.2	Information changed in the following parameters DNase & RNase free, ATP Assay, Non-Pyrogenic Statement, Nucleic acid free	01-2023