

Certificate of Conformity

Catalogue Number	See list
Description	J.T.Baker Robotic Tips, sterile, blistered
Country of Origin	Manufactured in Germany
Date of Issue (dd/mm/yyyy)	28/04/2023

Catalogue Number	Item Description	Volume
49106-3106	ROBOTIP TEC50NC F S S-T BL CS2304 IVD	50 µL
49106-1106	ROBOTIP TEC50NC F S S-T BL CS2304	50 µL
49006-3106	ROBOTIP TEC50C F S S-T BL CS2304 IVD	50 µL
49006-1106	ROBOTIP TEC50C F S S-T BL CS2304	50 µL
49006-3107	ROBOTIP TEC50C F S C-T BL CS2304 IVD	50 µL
49006-1107	ROBOTIP TEC50C F S C-T BL CS2304	50 µL
49102-3106	ROBOTIP TEC200NC F S S-T BL CS2304 IVD	200 µL
49102-1106	ROBOTIP TEC200NC F S S-T BL CS2304	200 µL
49002-3106	ROBOTIP TEC200C F S S-T BL CS2304 IVD	200 µL
49002-1106	ROBOTIP TEC200C F S S-T BL CS2304	200 µL
49002-3107	ROBOTIP TEC200C F S C-T BL CS2304 IVD	200 µL
49002-1107	ROBOTIP TEC200C F S C-T BL CS2304	200 µL
49103-3106	ROBOTIP TEC1000NC F S S-T BL CS2304 IVD	1000 µL
49103-1106	ROBOTIP TEC1000NC F S S-T BL CS2304	1000 µL
49033-3106	ROBOTIP TEC1000C F S WB S-T BL CS2304 IVD	1000 µL
49033-1106	ROBOTIP TEC1000C F S WB S-T BL CS2304	1000 µL
49003-3106	ROBOTIP TEC1000C F S S-T BL CS2304 IVD	1000 µL
49003-1106	ROBOTIP TEC1000C F S S-T BL CS2304	1000 µL
49003-3107	ROBOTIP TEC1000C F S C-T BL CS2304 IVD	1000 µL
49003-1107	ROBOTIP TEC1000C F S C-T BL CS2304	1000 µL
49000-3106	ROBOTIP STR300C F S BL CS2304 IVD	300 µL
49000-1106	ROBOTIP STR300C F S BL CS2304	300 µL
49001-3106	ROBOTIP STR1100C F S BL CS2304 IVD	1100 µL
49001-1106	ROBOTIP STR1100C F S BL CS2304	1100 µL

Catalogue Number	Item Description	Volume
49010-1015	ROBOTIP HAM50C NF S BL HT2 CS5760	50 µL
49010-3005	ROBOTIP HAM50C NF S BL CS5760 IVD	50 µL
49010-1005	ROBOTIP HAM50C NF S BL CS5760	50 µL
49010-1115	ROBOTIP HAM50C F S BL HT2 CS5760	50 µL
49010-3105	ROBOTIP HAM50C F S BL CS5760 IVD	50 µL
49010-1105	ROBOTIP HAM50C F S BL CS5760	50 µL
49008-1015	ROBOTIP HAM300C NF S BL HT2 CS5760	300 µL
49008-3005	ROBOTIP HAM300C NF S BL CS5760 IVD	300 µL
49008-1115	ROBOTIP HAM300C F S BL HT2 CS5760	300 µL
49008-3105	ROBOTIP HAM300C F S BL CS5760 IVD	300 µL
49008-1105	ROBOTIP HAM300C F S BL CS5760	300 µL
49009-1015	ROBOTIP HAM1000C NF S BL HT2 CS3840	1000 µL
49009-3005	ROBOTIP HAM1000C NF S BL CS3840 IVD	1000 µL
49009-1005	ROBOTIP HAM1000C NF S BL CS3840	1000 µL
49009-1115	ROBOTIP HAM1000C F S BL HT2 CS3840	1000 µL
49009-3105	ROBOTIP HAM1000C F S BL CS3840 IVD	1000 µL
49009-1105	ROBOTIP HAM1000C F S BL CS3840	1000 µL

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

Tips: Polypropylene
 Tray and S-tray: Polycarbonate or C-tray: Polypropylene
 Filter: Polyethylene

Manufacturing Environment

Robotic tips are manufactured under clean room conditions according to DIN EN ISO 14644-1:2016-06.

Sterilization

Products are EB (Electron beam) irradiated and dose released upon ISO 11137-2:2013 recommended practices in effect at the time of validation



meet the requirement of 10^{-6} SAL.

ATP Assay	Products are tested with detection level $< 1 \times 10^{-12}$ mmol.
PCR inhibitors Free	Product yield equivalent to control < 10 amplifiable targets
Human DNA Free	Products are tested with detection level < 1 pg
DNase & RNase Free	Products are tested with detection level $< 1 \times 10^{-6}$ KunitzU (DNase) and $< 1 \times 10^{-9}$ KunitzU (RNase)
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).
Cytotoxicity	Not applicable
Non-Pyrogenic Statement	Endotoxin free, tested with detection level < 0.02 EU/Unit
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	Please see RoHS information below.
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.
Material Statement	Not applicable
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.