

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)	25/03/2022

Catalogue Number	Item Description	Volume
49000-1106	Conductive tips 300 µL filter tray sterile	300 µL
49000-3106	Conductive tips 300 µL filter tray sterile IVD	300 µL
49001-1106	Conductive tips 1100 µL filter tray sterile	1100 µL
49001-3106	Conductive tips 1100 µL filter tray sterile IVD	1100 µL
49002-1106	Conductive tips 200 µL filter S-tray sterile	200 µL
49002-3106	Conductive tips 200 µL filter S-tray sterile IVD	200 µL
49002-1107	Conductive tips 200 µL filter C-tray sterile	200 µL
49002-3107	Conductive tips 200 µL filter C-tray sterile IVD	200 µL
49003-1106	Conductive tips 1000 µL filter S-tray sterile	1000 µL
49003-3106	Conductive tips 1000 µL filter S-tray sterile IVD	1000 µL
49003-1107	Conductive tips 1000 µL filter C-tray sterile	1000 µL
49003-3107	Conductive tips 1000 µL filter C-tray sterile IVD	1000 µL
49033-1106	Conductive tips 1000 µL wide bore filter S-tray sterile	1000 µL
49033-3106	Conductive tips 1000 µL wide bore filter S-tray sterile IVD	1000 µL
49006-1106	Conductive tips 50 µL filter S-tray sterile	50 µL
49006-3106	Conductive tips 50 µL filter S-tray sterile IVD	50 µL
49006-1107	Conductive tips 50 µL filter C-tray sterile	50 µL
49006-3107	Conductive tips 50 µL filter C-tray sterile IVD	50 µL
49102-1106	Non-conductive tips 200 µL filter S-tray sterile	200 µL
49102-3106	Non-conductive tips 200 µL filter S-tray sterile IVD	200 µL
49103-1106	Non-conductive tips 1000 µL filter S-tray sterile	1000 µL
49103-3106	Non-conductive tips 1000 µL filter S-tray sterile IVD	1000 µL
49106-1106	Non-conductive tips 50 µL filter S-tray sterile	50 µL
49106-3106	Non-conductive tips 50 µL filter S-tray sterile IVD	50 µL
49008-1105	Conductive tips 300 µL filter tray sterile	300 µL
49008-3105	Conductive tips 300 µL filter tray sterile IVD	300 µL
49009-1105	Conductive tips 1000 µL filter tray sterile	1000 µL
49009-3105	Conductive tips 1000 µL filter tray sterile IVD	1000 µL
49009-1005	Conductive tips 1000 µL tray sterile	1000 µL
49009-3005	Conductive tips 1000 µL tray sterile IVD	1000 µL
49010-1105	Conductive tips 50 µL filter tray sterile	50 µL
49010-3105	Conductive tips 50 µL filter tray sterile IVD	50 µL
49010-1005	Conductive tips 50 µL tray sterile	50 µL
49010-3005	Conductive tips 50 µL tray sterile IVD	50 µL

Quality System Compliance

Products are manufactured in **ISO 13485** and **ISO 9001** 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
IVD	Robotic tips are available with EC conformity declaration as accessories for clinical diagnostic applications.
Manufacturing Environment	Robotic tips are manufactured under clean room conditions according to DIN EN ISO 14644-1.
Sterilization	Products are EB (Electron beam) irradiated and dose released upon ISO 11137-2 recommended practices in effect at the time of validation meet the requirement of 10^{-6} SAL.
ATP Assay	Tested with detection level $< 1 \cdot 10^{-12}$
PCR inhibitors Free	Product yield equivalent to control < 10 amplifiable targets
Human DNA Free	Tested with detection level < 1 pg
DNase & RNase Free	Tested with detection level $< 1 \cdot 10^{-6}$ (DNase) and $< 1 \cdot 10^{-9}$ (RNase)
BSE/TSE	No use of any raw materials 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
Cytotoxicity	Not applicable
Non-Pyrogenic Statement	Not applicable
Latex Statement	Not applicable
BPA Statement	Not applicable
DEHP Statement	Not applicable
Endotoxine Free	Tested with detection level $< 0,02$
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: Ritter 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.
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