	Document number	Revision	Page	Date
			1 of 1	2024-1-23
PRODUCT DATA SHEET	**1 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 10.62 in. +/- 0.1 in., Tip OD – 0.09 in.,
max Working Volume – 1.3 mL, Pipette OD – 0.181 in.,
Tolerances of ID & OD – 0.016 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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,
“Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 1000 pcs
Weight of case 4.6 kg

This is the current specification for this product. innoME reserves the right to make changes, in full or in part, at any time without prior norification.

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	Document number	Revision	Page	Date
			1 of 1	2024-1-17
PRODUCT DATA SHEET	**2 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 10.63 in. +/- 0.1 in., Tip OD – 0.106 in.,
max Working Volume – 2.8 mL, Pipette OD – 0.248 in.,
Tolerances of ID & OD – 0.016 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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,
“Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 1000 pcs
Weight of case 6.5 kg

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			1 of 1	2024-1-17
PRODUCT DATA SHEET	**5 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 13.39 in. +/- 0.1 in., Tip OD – 0.126 in.,
max Working Volume – 7.5 mL, Pipette OD – 0.319 in.,
Tolerances of ID & OD – 0.016 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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, “Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 500 pcs
Weight of case 5.1 kg

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			1 of 1	2024-1-17
PRODUCT DATA SHEET	**10 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 13.58 in. +/- 0.1 in., Tip OD – 0.13 in.,
max Working Volume – 12.5 mL, Pipette OD – 0.394 in.,
Tolerances of ID & OD – 0.016 in., Mouthpiece OD – 0.311 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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,
“Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 500 pcs
Weight of case 6.5 kg

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	Document number	Revision	Page	Date
			1 of 1	2024-1-17
PRODUCT DATA SHEET	**25 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 13.46 in. +/- 0.1 in., Tip OD – 0.97 in.,
max Working Volume – 34 mL, Pipette OD – 0.563 in.,
Tolerances of ID & OD – 0.016 in., Mouthpiece OD – 0.319 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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, “Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 250 pcs
Weight of case 4.1 kg

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	Document number	Revision	Page	Date
			1 of 1	2024-1-17
PRODUCT DATA SHEET	**50 mL Serological Pipette**			

Component Materials:
Pipette – Polystyrene meets UPS, Class VI requirements for plastic containers and closures. Polystyrene meets USP Cytotoxicity Test.
Mouthpiece Plug – Polystyrene meets USP Cytotoxicity Test.
Ink – Yellow/ black meets USP Cytotoxicity Test.

Product Dimensions:
Total Length – 13.9 in. +/- 0.1 in., Tip OD – 0.22 in.,
max Working Volume – 57 mL, Pipette OD – 0.709 in.,
Tolerances of ID & OD – 0.016 in., Mouthpiece OD – 0.319 in.

Sterilization:
The product has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products – Requirements for validation and routine control – Radiation sterilization. Sterility Assureance Level: SAL 10^{-6}

Pyrogens:
The product has been tested and has met the cirteria established in the current version of ANSI/AAMI ST 72: Bacterial Endotoxins – Test meghodologies, routine testing, and alternative to batch testing. Results: less than 0.1 EU/mL.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product complies with the latest revision of EMEA/410/01 “Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products” by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

DNase/RNase Free:
Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/µL for DNase and 10^{-9} Kunitz units/µL for RNase.

Human DNA Free:
Tested by PCR method and found to be free of detectable human HDNA contamination.

Volumetric 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, “Plasticslaboratory ware Disposable serological pipettes”.

Quality Control Testing:
Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections aond inline tests are listed below:

- Visual Inspection – Pass
- Packaging Inspection – Pass
- Integrity Test – Pass

Lot or serial number Lot number

Packaging
Minimum order qty: 200 pcs
Weight of case 4.9 kg

This is the current specification for this product. innoME reserves the right to make changes, in full or in part, at any time without prior norification.