EU DECLARATION OF CONFORMITY

Product Name(s) / Trade Name(s)	MiSeq™Dx Instrument
Intended Purpose	The MiSeqDx instrument is intended for targeted sequencing of DNA libraries from human genomic DNA extracted from peripheral whole blood or formalin-fixed, paraffin-embedded (FFPE) tissue, when used with *in vitro* diagnostic (IVD) assays performed on the instrument. The MiSeqDx instrument is not intended for whole genome or *de novo* sequencing. The MiSeqDx instrument is to be used with registered and listed, cleared, or approved IVD reagents and analytical software.
REF	DX-410-1001
Basic UDI-DI (BUDI-DI)	0081627002MISEQQP

Product Name(s) / Trade Name(s)	MiSeq™Dx Reagent Kit v3
Intended Purpose	The Illumina MiSeqDx Reagent Kit v3 is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The MiSeqDx Reagent Kit v3 is intended for use with the MiSeqDx Instrument and analytical software.
REF	20037124
Basic UDI-DI (BUDI-DI)	0081627002KITV3PX

Product Name(s) / Trade Name(s)	MiSeq™Dx Reagent Kit v3 Micro
Intended Purpose	The Illumina MiSeqDx Reagent Kit v3 Micro is a set of reagents and consumables intended for sequencing of sample libraries when used with validated assays. The MiSeqDx Reagent Kit v3 Micro is intended for use with the MiSeqDx instrument and analytical software.
REF	20063860
Basic UDI-DI (BUDI-DI)	0081627002KITV3PX

Illumina, Inc.
5200 Illumina Way
San Diego, CA 92122
USA
SRN: US-MF-000013476

EC REP

Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
The Netherlands
SRN: NL-AR-000012614

We, Illumina, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices (Instrument and Reagents)
- Radio Equipment Directive 2014/53/EU (Instrument)
- RoHS Directive 2011/65/EU as amended by (EU) 2015/863 (Instrument) – Annex III exemptions apply

RISK CLASS:

☒ A ☐ B ☐ C ☐ D

CONFORMITY ROUTE:

Annex I & II+III of Regulation EU 2017/746; Self-Declaration

Common Specification (CS): N/A

Joe Mcmullen *Electronically signed by: Joe Mcmullen*
Reason: Approver
Date: May 25, 2023 14:04 PDT

May 25, 2023

E. Joseph Mcmullen
Sr. Director, Regulatory Affairs
Illumina, Inc.

Date

San Diego, CA

Issued in

Product Components:

MiSeq™Dx Reagent Kit v3; 20037124

- MiSeq™Dx Reagent Kit v3 1/2; 20036261
- MiSeq™Dx Reagent Kit v3 2/2; 20036262

MiSeq™Dx Reagent Kit v3 Micro; 20063860

- MiSeq™Dx Reagent kit v3 Micro 1/2 Micro; 20064640
- MiSeq™Dx Reagent kit v3 Micro 2/2 Micro; 20064641

200019958_01_MiSeqDx_IVDR_Declaration_of_Conformity_May 25.2023

Final Audit Report 2023-05-25

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