

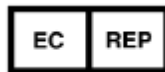
EU DECLARATION OF CONFORMITY

Product Name / Trade Name	Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (16 samples)
REF	20051354
Basic UDI-DI (BUDI-DI)	0081627002IDPENV
Product Name / Trade Name	Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (16 samples)
REF	20051355
Basic UDI-DI (BUDI-DI)	0081627002IDPENV
Product Name / Trade Name	Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (96 samples)
REF	20051352
Basic UDI-DI (BUDI-DI)	0081627002IDPENV
Product Name / Trade Name	Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (96 samples)
REF	20051353
Basic UDI-DI (BUDI-DI)	0081627002IDPENV
Product Name / Trade Name	Local Run Manager DNA GenerateFASTQ Dx Module for MiSeqDx
REF	20063022
Basic UDI-DI (BUDI-DI)	0081627002IDPESWRF
Product Name / Trade Name	Local Run Manager DNA GenerateFASTQ Dx Module for NextSeq 550Dx
REF	20063024
Basic UDI-DI (BUDI-DI)	0081627002IDPESWRF

Product Name / Trade Name	DRAGEN for Illumina Prep with Enrichment Dx for NovaSeq 6000Dx
Basic UDI-DI (BUDI-DI)	20074609 0081627002IDPESWRF
Product Name / Trade Name	DRAGEN for Illumina Prep with Enrichment Dx for NextSeq 550Dx
Basic UDI-DI (BUDI-DI)	20074730 0081627002IDPESWRF
Intended Purpose	The Illumina DNA Prep with Enrichment Dx Kit is a set of reagents and consumables used to prepare sample libraries from genomic DNA derived from human cells and tissue to develop in vitro diagnostic assays. User-supplied probe panels are required for the preparation of libraries targeting specific genomic regions of interest. The generated sample libraries are intended for use on Illumina's sequencing systems. The Illumina DNA Prep with Enrichment Dx includes software for sequencing run setup, monitoring, and analysis.



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



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

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: Feb 12, 2024 15:41 PST

February 12, 2024

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

Date

San Diego, CA

Issued in

Product Component List

Product Name: Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (16 samples), 20051354

Product Components : See below

Component Name	Part Number
Illumina Prep Dx Tagmentation Reagents 1	20050020
Illumina DNA Prep Dx Tagmentation Reagents 2	20050021
Illumina DNA Prep Dx Tagmentation Reagents 3	20050022
Illumina DNA Prep Dx Enrichment Reagents 1	20050023
Illumina DNA Prep Dx Enrichment Reagents 2	20050024
Illumina Unique Dual Index Dx Set A (96 Indexes)	20050038

Product Name: Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (16 samples), 20051355

Product Components : See below

Component Name	Part Number
Illumina Prep Dx Tagmentation Reagents 1	20050020
Illumina DNA Prep Dx Tagmentation Reagents 2	20050021
Illumina DNA Prep Dx Tagmentation Reagents 3	20050022
Illumina DNA Prep Dx Enrichment Reagents 1	20050023
Illumina DNA Prep Dx Enrichment Reagents 2	20050024
Illumina Unique Dual Index Dx Set B (96 Indexes)	20050039

Product Name: Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (96 samples), 20051352

Product Components : See below

Component Name	Part Number
Illumina Prep Dx Tagmentation Reagents 1	20050025
Illumina DNA Prep Dx Tagmentation Reagents 2	20050026
Illumina DNA Prep Dx Tagmentation Reagents 3	20050027
Illumina DNA Prep Dx Enrichment Reagents 1	20050028
Illumina DNA Prep Dx Enrichment Reagents 2	20050029
Illumina Prep Dx Cleanup Beads	20050030
Illumina Unique Dual Index Dx Set A (96 Indexes)	20050038

Product Name: Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (96 samples), 20051353

Product Components : See below

Component Name	Part Number
Illumina Prep Dx Tagmentation Reagents 1	20050025
Illumina DNA Prep Dx Tagmentation Reagents 2	20050026
Illumina DNA Prep Dx Tagmentation Reagents 3	20050027
Illumina DNA Prep Dx Enrichment Reagents 1	20050028
Illumina DNA Prep Dx Enrichment Reagents 2	20050029
Illumina Prep Dx Cleanup Beads	20050030
Illumina Unique Dual Index Dx Set B (96 Indexes)	20050039

200021206_02_Illumina_DNA_Prep_with_Enrichment_Dx_Declaration_of_Conformity

Final Audit Report


2024-02-12

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