

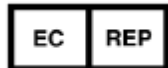
EU DECLARATION OF CONFORMITY

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
REF	20074609
Basic UDI-DI (BUDI-DI)	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. 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.



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 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: Sep 27, 2022 10:30 PDT

September 27, 2022

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

Date

San Diego, CA

Issued in






200021206_01_Illumina DNA Prep with Enrichment Dx_Declaration_of_Conformity

Final Audit Report

2022-09-27

Created:	2022-09-27
By:	Sheela Thirupathirajan (sthirupathirajan@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAALpiz1Y8KNHm5H2I3Ej3q0-Rp3HJUMwls

"200021206_01_Illumina DNA Prep with Enrichment Dx_Declaration_of_Conformity" History

-  Document created by Sheela Thirupathirajan (sthirupathirajan@illumina.com)
2022-09-27 - 4:47:23 PM GMT
-  Document emailed to Joe McMullen (jmcullen@illumina.com) for signature
2022-09-27 - 4:48:08 PM GMT
-  Joe McMullen (jmcullen@illumina.com) verified identity with Adobe Acrobat Sign authentication
2022-09-27 - 5:30:46 PM GMT
-  Document e-signed by Joe McMullen (jmcullen@illumina.com)
Signing reason: Approver
Signature Date: 2022-09-27 - 5:30:46 PM GMT - Time Source: server
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