

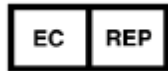
EU DECLARATION OF CONFORMITY

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

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.
-------------------------	---



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: Jun 9,
2022 10:45
PDT

09-Jun-2022

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

Date

San Diego, CA

Issued in






200021206_00_Illumina DNA Prep with Enrichment Dx_Declaration_of_Conformity

Final Audit Report

2022-06-09

Created:	2022-06-09
By:	Sheela Thirupathirajan (sthirupathirajan@illumina.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA_h-BFighEZH4aSw1y2-2Ki5iwoPbUjhg

"200021206_00_Illumina DNA Prep with Enrichment Dx_Declaration_of_Conformity" History

-  Document created by Sheela Thirupathirajan (sthirupathirajan@illumina.com)
2022-06-09 - 5:40:55 PM GMT- IP address: 192.84.34.99
-  Document emailed to Joe McMullen (jmcullen@illumina.com) for signature
2022-06-09 - 5:42:27 PM GMT
-  Joe McMullen (jmcullen@illumina.com) verified identity with Adobe Acrobat Sign authentication
2022-06-09 - 5:45:52 PM GMT
-  Document e-signed by Joe McMullen (jmcullen@illumina.com)
Signature Date: 2022-06-09 - 5:45:52 PM GMT - Time Source: server- IP address: 192.84.34.83
-  Agreement completed.
2022-06-09 - 5:45:52 PM GMT