

IZJAVA EU O SKLADNOSTI

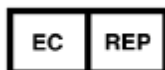
Ime izdelka/trgovsko ime	Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (16 samples)
REF	20051354
Osnovni UDI-DI (BUDI-DI)	0081627002IDPENV
Ime izdelka/trgovsko ime	Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (16 samples)
REF	20051355
Osnovni UDI-DI (BUDI-DI)	0081627002IDPENV
Ime izdelka/trgovsko ime	Illumina DNA Prep with Enrichment Dx with UD Indexes Set A (96 samples)
REF	20051352
Osnovni UDI-DI (BUDI-DI)	0081627002IDPENV
Ime izdelka/trgovsko ime	Illumina DNA Prep with Enrichment Dx with UD Indexes Set B (96 samples)
REF	20051353
Osnovni UDI-DI (BUDI-DI)	0081627002IDPENV
Ime izdelka/trgovsko ime	Local Run Manager DNA GenerateFASTQ Dx Module for MiSeqDx
REF	20063022
Osnovni UDI-DI (BUDI-DI)	0081627002IDPESWRF
Ime izdelka/trgovsko ime	Local Run Manager DNA GenerateFASTQ Dx Module for NextSeq 550Dx
REF	20063024
Osnovni UDI-DI (BUDI-DI)	0081627002IDPESWRF
Ime izdelka/trgovsko ime	DRAGEN for Illumina Prep with Enrichment Dx for NovaSeq 6000Dx
REF	20074609
Osnovni UDI-DI (BUDI-DI)	0081627002IDPESWRF

Predviden namen

Illumina DNA Prep with Enrichment Dx Kit je komplet reagentov in potrošnega materiala za pripravo knjižnic vzorcev iz genomskega DNK, pridobljenega iz človeških celic in tkiva. Za pripravo knjižnic, usmerjenih na določene genomske regije, potrebujete plošče s sondami, ki jih dobavi uporabnik. Ustvarjene knjižnice vzorcev so namenjene za uporabo s sistemi za sekvenciranje družbe Illumina.



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

Družba Illumina kot proizvajalec pripomočka(-ov) prevzema izključno odgovornost in izjavlja, da zgoraj navedeni izdelek(-i) izpolnjuje(-jo) določbe naslednjih uredb/direktiv:

- Uredba EU 2017/746 o *in vitro* diagnostičnih medicinskih pripomočkih

RAZRED TVEGANJA:

A B C D

POSTOPEK UGOTAVLJANJA SKLADNOSTI:

Priloga I in II+III Uredbe EU 2017/746; lastna izjava

Skupna specifikacija (CS): Ni na voljo

Joe McMullen

Electronically signed by: Joe McMullen
Reason: Approver
Date: Sep 27, 2022 10:30 PDT

27. september 2022

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

Datum

San Diego, CA

Izdano v






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:	CBJCHBCAABAALpiz1Y8KNHm5H2l3Ej3q0-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
-  Agreement completed.
2022-09-27 - 5:30:46 PM GMT