


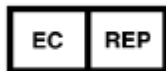
EU DECLARATION OF CONFORMITY

<p>Product Name(s) / Trade Name(s)</p>	<p>NovaSeq™ 6000Dx Instrument</p>
<p>Intended Purpose</p>	<p>The NovaSeq 6000Dx instrument is intended for sequencing of DNA libraries when used with in vitro diagnostic (IVD) assays. The NovaSeq 6000Dx instrument is intended for use with specific registered, certified or approved IVD reagents and analytical software.</p>
<p style="text-align: center;">REF</p>	<p>20068232</p>
<p>Basic UDI-DI (BUDI-DI)</p>	<p>0081627002NSQX2</p>
<p>Product Name(s) / Trade Name(s)</p>	<p>NovaSeq™ 6000Dx S2 Reagent v1.5 Kit (300 cycles) NovaSeq™ 6000Dx S4 Reagent v1.5 Kit (300 cycles)</p>
<p>Intended Purpose</p>	<p>The NovaSeq 6000Dx Reagent Kit (300 cycles) (S2 or S4) and NovaSeq 6000Dx Buffer Cartridge (S2 or S4) are reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NovaSeq 6000Dx instrument and analytical software.</p>
<p style="text-align: center;">REF</p>	<p>20046931 20046933</p>
<p>Basic UDI-DI (BUDI-DI)</p>	<p>0081627002NSQKTTN</p>
<p>Product Name(s) / Trade Name(s)</p>	<p>NovaSeq™ 6000Dx S2 Buffer Cartridge NovaSeq™ 6000Dx S4 Buffer Cartridge</p>
<p>Intended Purpose</p>	<p>The NovaSeq 6000Dx Reagent Kit (300 cycles) (S2 or S4) and NovaSeq 6000Dx Buffer Cartridge (S2 or S4) are reagents and consumables intended for sequencing of sample libraries when used with validated assays. The kit is intended for use with the NovaSeq 6000Dx instrument and analytical software.</p>
<p style="text-align: center;">REF</p>	<p>20062292 20062293</p>
<p>Basic UDI-DI (BUDI-DI)</p>	<p>0081627002NSQBUFHX</p>

Product Name(s) / Trade Name(s)	NovaSeq™ 6000Dx Library Tube NovaSeq™ 6000Dx Library Tube, 24 pack
Intended Purpose	The NovaSeq 6000 Dx Library Tubes (single tube or 24 pack) are intended to hold sample libraries for sequencing when used with NovaSeq 6000Dx S2 or S4 reagent kits and validated assays. The library tube is intended for use with NovaSeq 6000Dx instrument.
	20062290 20062291
Basic UDI-DI (BUDI-DI)	0081627002NSQTUBECX



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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: Aug 23, 2023 11:49 PDT

August 23, 2023

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

Date

San Diego, CA

Issued in

Product Components:

NovaSeq™ 6000Dx S2 Reagent v1.5 Kit (300 cycles); 20046931

- NovaSeq 6000Dx S2 cluster cartridge; 20046934
- NovaSeq 6000Dx S2 SBS cartridge; 20046936
- NovaSeq 6000Dx S2 Flow Cell; 20045447

NovaSeq™ 6000Dx S4 Reagent v1.5 Kit (300 cycles); 20046933

- NovaSeq 6000Dx S4 cluster cartridge; 20046938
- NovaSeq 6000Dx S4 SBS cartridge; 20046940
- NovaSeq 6000Dx S4 Flow Cell; 20045448

NovaSeq™ 6000Dx S2 Buffer Cartridge; 20062292

- NovaSeq 6000Dx S2 Buffer Cartridge; 20046945

NovaSeq™ 6000Dx S4 Buffer Cartridge; 20062293

- NovaSeq 6000Dx S4 Buffer Cartridge; 20046947

NovaSeq™ 6000Dx Library Tube; 20062290

- NovaSeq 6000Dx Library Tube; 20046942

NovaSeq™ 6000Dx Library Tube, 24 pack; 20062291

- NovaSeq 6000Dx Library Tube, 24 pack; 20060177

200027832_01_NovaSeq 6000Dx_IVDR_Declaration_of_Conformity

Final Audit Report


2023-08-23

Created:	2023-08-23
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