DECLARATION OF CONFORMITY

Manufacturer: Illumina
5200 Illumina Way
San Diego, CA 92122
United States

European Authorized Representative: Illumina Netherlands B. V.
Freddy van Riemsdijkweg 15
5657EE Eindhoven
Netherlands

Device Name: MiSeqDx Cystic Fibrosis 139-Variant Assay (20 runs)
MiSeqDx Cystic Fibrosis 139-Variant Assay (2 runs)
MiSeqDx Cystic Fibrosis Clinical Sequencing Assay

Device Model/Catalogue Number: DX-102-1003 DX-102-1004; DX-102-1001

Basic UDI-DI: 0081627002Cystf1b8c

Classification: General IVD


We, Illumina, declare under our sole responsibility that the in vitro Diagnostic Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Directive 98/79/EC (including amendments issued in the years following) which apply to them.

This declaration is supported by the EC Quality System Certificate(s) according to the provisions of relevant Annex(es) of this Directive. This declaration applies to all devices specified within this Declaration of Conformity and distributed onwards from the signature date below.

Authorized by:  

[Signature] 
Bryan Schneider 
Associate Director, Regulatory Affairs - HQ

15-APR-2020

Date (DD-MMM-YYYY)
Device Component List

Device Name: MiSeqDx Cystic Fibrosis System

Device Components:

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Part number</th>
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<tbody>
<tr>
<td>MiSeqDx Cystic Fibrosis 139-Variant Assay</td>
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<tr>
<td>MiSeqDx Cystic Fibrosis 139-Variant Assay (2-run; 96 samples) (ordering catalog DX-102-1004)</td>
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<td>MiSeqDx Cystic Fibrosis 139-Variant Assay (20-run; 960 samples) (ordering catalog DX-102-1003)</td>
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<td>MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (ordering catalog DX-102-1001)</td>
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