EU DECLARATION OF CONFORMITY

Product Name / Trade Name	TruSight Cystic Fibrosis
REF	20036925
BUDI-DI	0081627002CYSTFIB8C

INTENDED PURPOSE

TruSight Cystic Fibrosis 139-Variant Assay:

The TruSight Cystic Fibrosis 139-Variant Assay is a qualitative *in vitro* diagnostic system used to simultaneously detect 139 clinically relevant cystic fibrosis disease-causing mutations and variants of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene in genomic DNA isolated from human peripheral whole blood specimens. The variants include those recommended in 2004 by the American College of Medical Genetics (ACMG)[1] and in 2011 by the American College of Obstetricians and Gynecologists (ACOG)[2] The test is intended for carrier screening in adults of reproductive age, in confirmatory diagnostic testing of newborns and children, and as an initial test to aid in the diagnosis of individuals with suspected cystic fibrosis. The results of this test are intended to be interpreted by a board-certified clinical molecular geneticist or equivalent and should be used in conjunction with other available laboratory and clinical information.

This test is not indicated for use for newborn screening, fetal diagnostic testing, preimplantation testing, or for stand-alone diagnostic purposes.

The test is intended to be used on the Illumina MiSeqDx Instrument.

[1] Watson MS, Cutting GR, Desnick RJ, Driscoll DA, Klinger K, et al. (2004) Cystic fibrosis population carrier screening: 2004 revision of American College of Medical Genetics mutation panel. Genetics in Medicine 6(5):387–391.

[2] Committee on Genetics. (April 2011) The American College of Obstetricians and Gynecologists Committee Opinion. Update on Carrier Screening for Cystic Fibrosis 486: 1–4.

TruSight Cystic Fibrosis Clinical Sequencing Assay:

The TruSight Cystic Fibrosis Clinical Sequencing Assay is a targeted sequencing *in vitro* diagnostic system that resequences the protein coding regions and intron/exon boundaries of the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene in genomic DNA isolated from human peripheral whole blood specimens collected in K_2EDTA. The test detects single nucleotide variants, and small indels within the region sequenced, and additionally reports on two deep intronic mutations and two large deletions. The test is intended to be used on
the Illumina MiSeqDx Instrument.

The test is intended to be used as an aid in the diagnosis of individuals with suspected cystic fibrosis (CF). This assay is most appropriate when the patient has an atypical or non-classic presentation of CF or when other mutation panels have failed to identify both causative mutations. The results of the test are intended to be interpreted by a board-certified clinical molecular geneticist or equivalent and should be used in conjunction with other available information including clinical symptoms, other diagnostic tests, and family history.

This test is not indicated for use for stand-alone diagnostic purposes, fetal diagnostic testing, for preimplantation testing, carrier screening, newborn screening, or population screening.

Illumina, Inc.
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SRN: US-MF-000013476

EC REP

Illumina Netherlands B.V.
Steenoven 19
5626 DK Eindhoven
The Netherlands
SRN: NL-AR-000012614

We, Illumina, Inc., 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 (IVDR)

RISK CLASS: ☐ A ☐ B ☒ C ☐ D

CONFORMITY ROUTE:	ANNEX IX - Full Quality System
EU CERTIFICATE:	IVDR 734191
NAME OF NOTIFIED BODY:	BSI Group The Netherlands B.V.
NOTIFIED BODY IDENTIFICATION:	2797
COMMON SPECIFICATION (CS):	N/A

Joe Mcmullen

Electronically signed by: Joe Mcmullen
Reason: Approver
Date: Dec 13, 2023 09:17 PST

13-DEC-2023

E. Joseph McMullen
Regulatory Affairs
Illumina, Inc.

Date (dd-MMM-yyyy)

Issued in: San Diego, CA 92122 (USA)

Components:

- **TruSight Cystic Fibrosis Library Prep**:
  - TruSight Cystic Fibrosis Library Prep 1/3; 20036244
  - TruSight Cystic Fibrosis Library Prep 2/3; 20036209
  - TruSight Cystic Fibrosis Library Prep 3/3; 20036250
- **Local Run Manager CF Clinical Seq 2.0 Analysis Module; 20046734**
- **Local Run Manager CF Clinical Seq 2.0 Micro Analysis Module; 20072974**
- **Local Run Manager CF 139 Variant Analysis Module; 20046734**
- **Local Run Manager CF 139 Variant 2.0 Micro Analysis Module; 20072975**

TruSight CF IVDR DoC

Final Audit Report 2023-12-13

Created:	2023-12-13
By:	Bryan Schneider (bschneider@illumina.com)
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"TruSight CF IVDR DoC" History

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