

NUMBER:	TCF0000509
EFFECTIVE DATE:	21-Feb-2023
REVISION:	02.00
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**TITLE: Applied Biosystems™ 3500 Dx/3500xL Dx Genetic Analyzers EU Declaration of Conformity (IVDR)**

## EU DECLARATION OF CONFORMITY

Manufacturer's Name: Life Technologies Holdings Pte Ltd

Manufacturer's Address: Block 33, #07-06  
Marsiling Industrial Estate Road 3  
Singapore 739256

SRN (Single Registration Number): SG-MF-000023931

Life Technologies Holdings Pte Ltd declares that the *In Vitro* Diagnostic Medical Devices listed on the following pages are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on *In Vitro* Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

This EU Declaration of Conformity is issued under the sole responsibility of Life Technologies Holdings Pte Ltd.

Basic UDI-DI: Refer to Attachment A

Product and trade name: Applied Biosystems™ 3500 Dx/3500xL Dx Genetic Analyzers

Product catalogue number  
/or reference number: Refer to Attachment A

Photograph, other information: N/A

Conformity Assessment Route: Annex I & II+III

Risk Classification: Class A Rule 5 (b)

Notified Body Name: N/A

Notified Body Address: N/A

Notified Body Identification Number: N/A

EC Certificate (s) : N/A

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Product Description: Refer to Attachment A

Nomenclature: Refer to Attachment A

Life Technologies confirms that the products listed are manufactured under a controlled and approved Quality Management System that maintains a post market surveillance and vigilance procedure.

Approved by:



*Electronically signed by: Jinyao Su  
Reason: Approver of the GxP document  
Date: Feb 21, 2023 11:53 GMT+8*

Date: 21-Feb-2023

On behalf of Life Technologies Holdings Pte Ltd

Su Jinyao  
RA Manager  
Singapore

**Authorized Representative:**

Name: Life Technologies Europe B.V.  
Address: Kwartsweg 2  
2665 NN  
Bleiswijk  
The Netherlands  
SRN: NL-AR-000021890

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Attachment – List of products covered in this Declaration of Conformity that fulfill the IVDR requirements for CE marking:

Product catalogue number /or reference number, as applicable	Product name and Trade name	Intended purpose and/or product description	Basic UDI-DI	EMDN Code	GMDN Code
*A27856	3500xL Dx Genetic Analyzer consists of 3500xL Dx Genetic Analyzer (4405183) and 3500 Dx Series Data Collection Software 3 IVD v3.0.1 (A48698)	The automated 3500 Dx and 3500xL Dx Genetic Analyzers are capillary electrophoresis-based in vitro diagnostic devices intended to perform fluorescence-based sequencing and fragment analysis of nucleic acids in human derived specimens. The 3500 Dx and 3500xL Dx Genetic Analyzers are intended to be used by trained professionals in combination with in vitro diagnostic assays.	0190302TCF00005084L	W02050116	48031
*A27772	3500 Dx Genetic Analyzer consists of 3500 Dx Genetic Analyzer (4405182) and 3500 Dx Series Data Collection Software 3 IVD v3.0.1 (A48698)			W02050116	48031
4405183	3500xL Dx Genetic Analyzer			W02050116	48031
4405182	3500 Dx Genetic Analyzer			W02050116	48031
A49698	3500 Dx Series Data Collection Software 3 IVD v3.0.1			W02050182	43472

\* Combo SKUs: Catalog number is used for customer ordering purposes and does not carry a label

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Product catalogue number /or reference number, as applicable	Product name and Trade name	Manufacturing Site
*A27856	3500xL Dx Genetic Analyzer consists of 3500xL Dx Genetic Analyzer (4405183) and 3500 Dx Series Data Collection Software 3 IVD v3.0.1 (A48698)	Hitachi Japan South San Francisco
*A27772	3500 Dx Genetic Analyzer consists of 3500 Dx Genetic Analyzer (4405182) and 3500 Dx Series Data Collection Software 3 IVD v3.0.1 (A48698)	Hitachi Japan South San Francisco
4405183	3500xL Dx Genetic Analyzer	Hitachi Japan
4405182	3500 Dx Genetic Analyzer	Hitachi Japan
A49698	3500 Dx Series Data Collection Software 3 IVD v3.0.1	South San Francisco

Physical Manufacturing Sites

**Instrument**

Hitachi High Technologies (HHT) Corporation  
Naka Manufacturing Division,  
882 Ichige, Hitachinaka-shi,  
Ibaraki-ken 312-8504, Japan

**Software**

200 Oyster Point Blvd., South San Francisco, California 94080 USA

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Final Audit Report

2023-02-21

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## "Clean Copy\_TCF0000509\_Rev02.00\_EU Declaration of Conformity\_3500DX 3500XL DX GENETIC ANALYZER (IVDR) PRJ0003388" History



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Document e-signed by Jinyao Su (jinyao.su@thermofisher.com)

Signing reason: Approver of the GxP document

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Agreement completed.

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