

NUMBER:	TCF0000504
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TITLE: 3500 DX/3500XL DX GENETIC ANALYZER REAGENTS AND CONSUMABLES (BLAZON) EU Declaration of Conformity

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: 3500 Dx/3500xL Dx Genetic Analyzer Reagents and Consumables

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 (a)

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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**TITLE: 3500 DX/3500XL DX GENETIC ANALYZER REAGENTS AND CONSUMABLES
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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 8, 2023 12:01 GMT+8

Date: 08-Feb-2023

On behalf of <Life Technologies Holdings Pte Ltd>

Su Jinyao
RA Manager
Singapore

Authorized Representative, if applicable:

Name: Life Technologies Europe B.V.
Address: Kwartsweg 2
2665 NN
Bleiswijk
The Netherlands

SRN: NL-AR-000021890

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

<i>Product catalogue number /or reference number, as applicable</i>	<i>Product name and Trade name</i>	<i>Intended purpose and/or product description</i>	<i>Basic UDI-DI</i>	<i>EMDN Code</i>	<i>GMDN Code</i>
4393709	POP-7™ (384) Performance Optimized Polymer 3500 Dx Series	The POP-6™ /POP-7™ Polymer is intended for <i>in vitro</i> diagnostic use to separate fluorescently labelled DNA fragments during capillary electrophoresis runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031
4393711	POP-6™ (960) Performance Optimized Polymer 3500 Dx Series			W02050185	48031
4393713	POP-7™ (960) Performance Optimized Polymer 3500 Dx Series			W02050185	48031
4393716	POP-6™ (384) Performance Optimized Polymer 3500 Dx Series			W02050185	48031

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4393925	Anode Buffer Container 3500 Dx Series	The Anode Buffer Container (ABC) is intended for <i>in vitro</i> diagnostic use to support capillary electrophoresis runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	58237
4410716	3500 Dx Series Septa Cathode Buffer Container	The Septa Cathode Buffer Container is intended for sealing the Cathode Buffer Container (CBC) used with the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	58237
4408258	Cathode Buffer Container 3500 Dx Series	The Cathode Buffer Container (CBC) is intended for <i>in vitro</i> diagnostic use to support capillary electrophoresis runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	58237

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4409543	Conditioning Reagent 3500 Dx Series	The Conditioning Reagent is intended for <i>in vitro</i> diagnostic use with the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. It is used to prime the polymer pump, wash the polymer pump between polymer type changes, and perform instrument shutdown procedures. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	60120
4404307	Hi-Di™ Formamide 3500 Dx Series	The Hi-Di™ Formamide is intended for <i>in vitro</i> diagnostic use as an injection solvent on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	60120
4440752	Hi-Di™ Formamide 3500 Dx Series 4x5mL			W02050185	60120

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4404682	3500 Dx Capillary Array 36cm	Capillary Arrays are intended for <i>in vitro</i> diagnostic use in capillary electrophoresis runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031
4404684	3500 Dx Capillary Array 50cm			W02050185	48031
4404686	3500xL Dx Capillary Array 36cm			W02050185	48031
4404688	3500xL Dx Capillary Array 50cm			W02050185	48031
4410227	3500 Dx Series 96-Well Standard Retainer & Base Set	The 96-Well Standard Retainer & Base Set is intended to hold a 96-well sample plate (standard) when placed on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031
4410230	3500 Dx Series 8-Tube Standard Retainer & Base Set	The 8-Tube Standard Retainer & Base Set is intended to hold a strip-tube (standard) when placed on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031

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4410234	3500 Dx Series 384-Well Standard Retainer & Base Set	The 384-Well Standard Retainer & Base Set is intended to hold a 384-well sample plate (standard) when placed on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031
4410700	3500 Dx Series Septa 96-Well	Septa are intended to close sample plates and strips before they are inserted into the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	48031

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4410702	3500 Dx Series 8-Strip Septa	<p>Septa are intended to close sample plates and strips before they are inserted into the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications.</p> <p>The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators</p>	0190302TCF00005034A	W02050185	48031
4410232	3500 Dx Series 8-Tube Fast (0.1 mL) Retainer & Base Set	<p>The 8-Tube Fast Retainer & Base Set is intended to hold a strip-tube (fast) when placed on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications.</p> <p>The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators</p>	0190302TCF00005034A	W02050185	48031

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4410607	3500 Dx Series 384-Well Septa	<p>Septa are intended to close sample plates and strips before they are inserted into the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications.</p> <p>The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators</p>	0190302TCF00005034A	W02050185	48031
4410229	3500 Dx Series 96-Well Fast (0.1 mL) Retainer & Base Set	<p>The 96-Well Fast Retainer & Base Set is intended to hold a 96-well sample plate (fast) when placed on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications.</p> <p>The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators</p>	0190302TCF00005034A	W02050185	48031

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4404310	Sequencing Standard BigDye™ Terminator V3.1-Dx	The Sequencing Standard BigDye™ Terminator v3.1 is intended for spectral calibration and performing control sequencing runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	41906
4462113	Sequencing Standard BigDye™ Terminator V1.1-Dx	The Sequencing Standard BigDye™ Terminator v1.1 is intended for spectral calibration and performing control sequencing runs on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	41906

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A25775	DS-33 Matrix Standard (Dye Set G5)-Dx	The DS-33 Matrix Standard (Dye Set G5)–Dx is intended to perform spectral calibrations required when analyzing 6-FAM™, VIC™, NED™, PET™, and LIZ™ dye-labeled DNA fragments on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	41906
A25793	DS-33 GeneScan™ Install Kit-Dx with GeneScan™ 600 LIZ™ V2.0	The Applied Biosystems™ DS-33 GeneScan™ Install Kit–Dx with GeneScan™ 600 LIZ™ v2.0 is intended to perform fragment analysis installation and verification checks on the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	41906

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A25794	GeneScan™ 600 LIZ™ Size Standard V2.0-Dx	The GeneScan™ 600 LIZ™ Size Standard v2.0-Dx is LIZ™ dye-labeled size standard intended for <i>in vitro</i> diagnostic use, for reproducible sizing of fragment analysis data with the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	41906
4462785	Polymer Pouch Caps, Dx	The Polymer Pouch Cap is intended to cover a polymer pouch if it is removed from the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	62625
4461875	Polymer Delivery Pump Cleaning Kit, Dx	The Polymer Delivery Pump Cleaning Kit is intended for performing any necessary polymer pump cleaning procedures during maintenance of the Applied Biosystems™ 3500 Dx and 3500xL Dx Genetic Analyzers. The product is not validated for use with other systems or applications. The Applied Biosystems 3500 Dx/3500xL Dx Genetic Analyzers are intended for use by trained operators	0190302TCF00005034A	W02050185	63377

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<i>Product catalogue number /or reference number, as applicable</i>	<i>Product name and Trade name</i>	<i>Manufacturing site</i>
4393709	POP-7™ (384) Performance Optimized Polymer 3500 Dx Series	Bedford
4393711	POP-6™ (960) Performance Optimized Polymer 3500 Dx Series	Bedford
4393713	POP-7™ (960) Performance Optimized Polymer 3500 Dx Series	Bedford
4393716	POP-6™ (384) Performance Optimized Polymer 3500 Dx Series	Bedford
4393925	Anode Buffer Container 3500 Dx Series	Bedford
4408258	Cathode Buffer Container 3500 Dx Series	Bedford
4409543	Conditioning Reagent 3500 Dx Series	Bedford
4404307	Hi-Di™ Formamide 3500 Dx Series	Bedford
4440752	Hi-Di™ Formamide 3500 Dx Series 4x5mL	Bedford
4404682	3500 Dx Capillary Array 36cm	Japan - Hitachi
4404684	3500 Dx Capillary Array 50cm	Japan - Hitachi
4404686	3500xL Dx Capillary Array 36cm	Japan - Hitachi
4404688	3500xL Dx Capillary Array 50cm	Japan - Hitachi
4410227	3500 Dx Series 96-Well Standard Retainer & Base Set	Japan - Hitachi
4410230	3500 Dx Series 8-Tube Standard Retainer & Base Set	Japan - Hitachi
4410234	3500 Dx Series 384-Well Standard Retainer & Base Set	Japan - Hitachi
4410700	3500 Dx Series Septa 96-Well	Japan - Hitachi
4410702	3500 Dx Series 8-Strip Septa	Japan - Hitachi
4410232	3500 Dx Series 8-Tube Fast (0.1 mL) Retainer & Base Set	Japan - Hitachi
4410607	3500 Dx Series 384-Well Septa	Japan - Hitachi
4410229	3500 Dx Series 96-Well Fast (0.1 mL) Retainer & Base Set	Japan - Hitachi
4410716	3500 Dx Series Septa Cathode Buffer Container	Japan - Hitachi
4404310	Sequencing Standard BigDye™ Terminator V3.1-Dx	Vilnius
4462113	Sequencing Standard BigDye™ Terminator V1.1-Dx	Vilnius
A25775	DS-33 Matrix Standard (Dye Set G5)-Dx	Vilnius
A25793	DS-33 GeneScan™ Install Kit-Dx with GeneScan™ 600 LIZ™ V2.0	Vilnius
A25794	GeneScan™ 600 LIZ™ Size Standard V2.0-Dx	Vilnius
4462785	Polymer Pouch Caps, Dx	Austin
4461875	Polymer Delivery Pump Cleaning Kit, Dx	Austin

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Physical Manufacturing Sites:

1. Hitachi High Technologies (HHT) Corporation
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3. Life Technologies Corporation
35 Wiggins Avenue
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4. Life Technologies Corporation,
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78744 United States





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Final Audit Report

2023-02-08

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