

NUMBER:	TCF0000564
EFFECTIVE DATE:	27-Apr-2023
REVISION:	01.00
PAGE:	1 of 3

**TITLE: VeritiPro™ Dx Thermal Cyclers 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: VeritiPro™ Dx Thermal Cyclers  
 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

NUMBER:	TCF0000564
EFFECTIVE DATE:	27-Apr-2023
REVISION:	01.00
PAGE:	2 of 3

**TITLE: VeritiPro™ Dx Thermal Cyclers EU Declaration of Conformity**

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: Apr 27, 2023 16:44 GMT+8*

Date: 27-Apr-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 22665 NN Bleiswijk  
The Netherlands  
NL-AR-000021890

NUMBER:	TCF0000564
EFFECTIVE DATE:	27-Apr-2023
REVISION:	01.00
PAGE:	3 of 3

**TITLE: VeritiPro™ Dx Thermal Cycler EU Declaration of Conformity**

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

**Attachment A**

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
A55826	VeritiPro™ Dx Thermal Cycler	The semi-automated Applied Biosystems™ VeritiPro™ Dx Thermal Cycler is an in vitro diagnostic device intended to amplify nucleic acid from human-derived specimens.	0190302TCF00005634U	W02039006	48031
* A57751	VeritiPro™ Dx 1 year Package Solution	The Applied Biosystems™ VeritiPro™ Dx Thermal Cycler is intended for use by trained professionals in laboratory techniques and procedures.			
* A57752	VeritiPro™ Dx 2 year Package Solution with planned maintenance				

\* SKU is used for customer ordering purposes and does not carry a label.