

## EU Declaration of Conformity

Manufacturer: **BIOCYTECH CORPORATION SDN BHD (854649-T)**  
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 The Netherlands  
 SRN: NL-AR-000000247

Notified Body: Not Applicable – Self Declared Class A IVD Medical Device

Brand Name: PathTezt®

Biocytech Corporation Sdn Bhd declares under its own responsibility that the product(s):

No.	Description	EMDN	Basic UDI-DI	Model Name	Model Number
1	PathTezt Processor	W0202059099	955102041ProcessorLR	Processor Model 2000	LBC-2009
				Infinity with AutoLoader	PTIA-2021
2	PathTezt Consumable - Preserved Cell Solution	W01030799	955102041CellH2	Preserve Cell Solution 20mL (Methanol Based)	PCS-200920
				Preserve Cell Solution 20mL (Ethanol Based)	PCS-200920E
				Preserve Cell Solution 10mL (Methanol Based)	PCS-200910
				Preserve Cell Solution 10mL (Ethanol Based)	PCS-200910E
				Preserve Cell Solution 10mL	PCS-200910B
				Preserve Cell Solution 5mL (Methanol Based)	PCS-200905
				Preserve Cell Solution 5mL (Ethanol Based)	PCS-200905E
				Preserve Cell Solution 3mL (Methanol Based)	PCS-200903
				Preserve Cell Solution 3mL (Ethanol Based)	PCS-200903E
				Preserve Cell Solution 1mL (Methanol Based)	PCS-200901
				Preserve Cell Solution 1mL (Ethanol Based)	PCS-200901E
				SelfSampler HPV Preserve Cell Solution 3mL	SSH-1003
EasyVial Preserve Cell Solution 15mL	EV-60010				

## EU Declaration of Conformity

				EasyVial Preserve Cell Solution 926mL	EV-926
				EasyVial Preserve Cell Solution 5mL	EV-60005
				EasyVial Preserve Cell Solution 10mL	EV-61000
				Non-Gyn Preserve Cell Solution 20mL	NGPCS-200920
				UrineCell Preserve Cell Solution 20mL	UCPCS-200920
				Preserve Cell Solution 926mL (Methanol Based)	PCS-926
				Preserve Cell Solution 926mL (Ethanol Based)	PCS-926E
				Cytolysis Solution 926mL	CTLS-9260604
				Density Reagent	PDR-1000
3	PathTezt Consumable - Filter	W05030402	955102041FilterXS	Gyn Filter	GF-0825100
				Non-Gyn Filter	NGF-0525100
				UrineCell Filter	UCF-0813100
				Pretreatment Kit (Pre-Filter)	PS-250
				Dual Filter	DF-2508
4	PathTezt Consumable - Slide	W0503900201	955102041SlideQL	Cyto-Slide	CS-36100
				Imager Slide	IS-36100
				UrineCell Slide	US-36100
				IHC Slide	HS-36100
				Cover Glass	CG-102450
				PreClean White Colour Glass Slide	GS-2500
5	Centrifuge Consumable	W02069085	955102041CentrifugeKP	Deposit Tube	DT-2100
				1000ul Natural Pipet Tips	TIPS-48096
				200ul Yellow Pipet Tips	TIPS-200
				Pipette Syringes	SP-500
				Centrifuge Tube	CT-500
				Settling Chamber	DSC-500

## EU Declaration of Conformity

6	Staining Consumable	W0599	955102041StainingJL	Staining Rack	L-30
				Staining Jar	LJ-30
				Sedprep System (10)	LBP-2010
				Sedprep System board (12)	LBP-2012

**Conformity Assessment Route:**

We herewith declare that the above-mentioned product(s) complies with requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in Vitro Diagnostic Medical Devices. Ex Article 48, point 10 and Annex VIII, 2.5 Rule 5 "devices classified as class A". Data provided in the technical file includes all knowledge and foreseeable risks which are expected to perform sufficiently to its intended used. Master copy of Technical File is retained by Biocytech Corporation Sdn Bhd's Managing Director. Copy of Technical File has been distributed to European Representative for submission to Competent Authority when requested. Any changes pertaining to Technical File shall be carried out as per the procedure Control of Documents and Records. All supporting documents are retained under the premises of the manufacturer.

**Norme applicate/Applied standards (\*):**

- EN ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- EN ISO 18113-1:2024 In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
- EN ISO 18113-2:2024 In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 2: In Vitro Diagnostic Reagents for Professional Use
- EN ISO 15223-1:2021 Medical Devices – Symbols To Be Used With Information To Be Supplied by the Manufacturer – Part 1: General Requirements
- EN ISO 23640:2015 In Vitro Diagnostic Medical Devices – Evaluation of Stability of In Vitro Diagnostic Reagents

Sincerely,



Name: Michelle Ng Yoke Fong

Position: Director

Date: 28/08/2025