



REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

CYMDA

Medical and Public Health Services
Cyprus Medical Devices Competent Authority

File No.: 5.23.005.13.9
Tel No.: 22 605574
Fax No: 22 605491

25 October 2024

To whom it may concern

Certificate of Free Sale for Exportation of Medical Products

This is to notify that **Medicover Genetics Limited** is a medical devices manufacturer located in Cyprus with contact details:

Manufacturer Details:	
Name:	Medicover Genetics Limited
SRN:	CY-MF-000009381
Address:	Neas Engomis 31, Engomi, 2409 Nicosia, Cyprus
Telephone:	+357 22 266 888
Email:	theodora.chrysostomou@medicover.com
Web Site:	www.medicover-genetics.com
Contact Person:	Mrs Theodora Chrysostomou

The products detailed in the attached schedule have been checked, registered and CE marked according to Regulation (EU) 2017/746 concerning In Vitro Medical Devices and therefore may be freely sold in all member states of the European Economic Area including Cyprus and are legally distributed around the world.

Please refer to "EU Declaration of Conformity" for full product description.



(Christiana Valianti)
for Cyprus Medical Devices
Competent Authority

Schedule: Product description

Product Details:	
Name:	TarCET KIT
Product Variants:	TarCET Metabolic Panel TarCET Aortopathy Panel TarCET Arrhythmia Panel TarCET Cardiomyopathy Panel TarCET Congenital Heart Defects Panel TarCET FH, PH and RAS Panel TarCET Cardiac Comprehensive Panel TarCET Hereditary Cancer Panel TarCET Infertility Panel TarCET Neonatal Panel TarCET Carrier Screening Core Panel TarCET Carrier Screening Comprehensive Panel
Basic UDI-DI:	52980048MULTITN
Risk Class:	A



EU DECLARATION OF CONFORMITY

Manufacturer Name:	MEDICOVER GENETICS LTD
Manufacturer Address:	31 Neas Engomis Str., 2409 Engomi, Nicosia, Cyprus
Single Registration Number (SRN):	CY-MF-000009381
Product Name(s):	TarCET KIT
Product Variant(s):	TarCET Kit Panels: <ul style="list-style-type: none">•TarCET Metabolic Panel•TarCET Aortopathy Panel•TarCET Arrhythmia Panel•TarCET Cardiomyopathy Panel•TarCET Congenital Heart Defects Panel•TarCET FH, PH and RAS Panel•TarCET Cardiac Comprehensive Panel•TarCET Hereditary Cancer Panel•TarCET Infertility Panel•TarCET Neonatal Panel•TarCET Carrier Screening Core Panel•TarCET Carrier Screening Comprehensive Panel
Intended Purpose:	TarCET Kit is a reagent kit including library preparation and targeted capture enrichment. The kit is intended for use with genomic DNA from human cells for library preparation and capture enrichment for Next-Generation Sequencing (NGS) applications. The kit can be used to target specific regions of the genome with validated DNA hybridization probe panels supplied in the kit. All further downstream analyses can be performed in conjunction with the IVD VEGA analysis software, not provided in this kit, or using an independent IVD analysis software.
Catalogue Numbers:	<ul style="list-style-type: none">• TarCET Metabolic Panel (Cat # ET201-00-2016)• TarCET Aortopathy Panel (Cat # ET203-00-2016)• TarCET Arrhythmia Panel (Cat # ET204-00-2016)• TarCET Cardiomyopathy Panel (Cat # ET205-00-2016)• TarCET Congenital Heart Defects Panel (Cat # ET206-00-2016)• TarCET FH, PH and RAS Panel (Cat # ET207-00-2016)• TarCET Cardiac Comprehensive Panel (Cat # ET210-00-2016)• TarCET Hereditary Cancer Panel (Cat # ET211-00-2016)• TarCET Infertility Panel (Cat # ET212-00-2016)• TarCET Neonatal Panel (Cat # ET213-00-2016)• TarCET Carrier Screening Core Panel (Cat # ET214-00-2016)

- TarCET Carrier Screening Comprehensive Panel (Cat # ET215-00-2016)

Basic UDI-DI: 52980048MULTITN

Name and ID of Notifying Body: Not Applicable

Risk Class: A

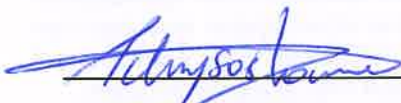
Conformity Route: Annex I, II & III of Regulation EU 2017/746; Self-declaration

Common Specification (CS): Not Applicable

EU certificate number: Not Applicable

We, Medicover Genetics Ltd., hereby declare under our sole responsibility, that the medical device(s) specified in this EU declaration is in conformity with the provisions of Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices.

Signed November 5th, 2024, in Nicosia:



MEDICOVER GENETICS LTD
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2409 Nicosia, Cyprus
HE 418406
VAT No:99000271A

Theodora Chrysostomou
Senior Regulatory & Quality Manager
Person Responsible for Regulatory Compliance
MEDICOVER GENETICS LTD