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: 22605735
Fax No: 22605491
E-Mail: cymda@mphs.moh.gov.cy

05 January 2023

To whom it may concern

Subject: Change of manufacturer's name

I am instructed on behalf of the Cyprus Medical Devices Competent Authority to inform you that as of 9th of August 2022, the manufacturer of ***TarCET IVD KIT*** has changed the name from "*NIPD Genetics Molecular Laboratories Limited*" to "***Medicover Genetics Limited***". The physical address of the manufacturing plant remains unchanged.

This change is not a significant change under Regulation (EU) 2017/746 and therefore *TarCET IVD KIT* is still subject to the transitional provisions of article 110 (3) of Regulation (EU) 2017/746.

The Cyprus Medical Devices Competent Authority is at your disposal for any further clarifications.

(C. Valianti)
for Cyprus Medical Devices
Competent Authority

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: 22605735
Fax No: 22605491
E-Mail: cymda@mphs.moh.gov.cy

23 May 2022

NIPD Genetics Molecular Laboratories Limited
31 Neas Engomis Str., Engomi,
2409 Nicosia, Cyprus
Tel: +357 22 266888
Fax: +357 22 266889
Email: p.patsalis@nipd.com
t.chrysostomou@nipd.com
(Attn: Dr. Philippos Patsalis
Mrs Theodora Chrysostomou)

Subject: Registration of persons responsible for placing on the Market Medical Devices according to Directive 98/79/EC and Regulation 597/2003 of Republic of Cyprus

I am instructed on behalf of the Cyprus Medical Devices Authority to inform you that *Manufacturer Name:-* ***NIPD Genetics Molecular Laboratories Limited,*** located at *Manufacturer Address:-* ***31 Neas Engomis Str., Engomi, 2409 Nicosia, Cyprus*** has been added to the Medical Devices Manufacturers Registry as the manufacturer of the *product:-* ***TarCET IVD KIT*** *classification of the concerned devices:-* ***Other General IVD.***

Your registration is based upon your declaration on your application form dated 02/05/2022 and means that you should now be operating under the on In Vitro Diagnostic Medical Devices Directive 98/79/EC and Regulation 597/2003 of Republic of Cyprus for the products you asked us to register, by fully complying with the essential requirements, CE marking these products or labelling them as such.

Please inform us of any changes to the company information, or to the technical file of the products before its implementation. Additional editions of products or modifications of the products that are not included in the technical file are not considered as approved by the Competent Authority to be placed on the market. If you stop placing devices on the market you should inform us so that we can amend our records.

It is noted that the Competent Authority may change its decision in the event that new information is brought to its attention.

The Medical Devices Competent Authority of Cyprus is at your disposal for any further clarifications.

(C. Valianti)
for Cyprus Medical Devices
Competent Authority