MEDICOVER
GENETICS

07/03/2023

Subject: Product catalogue number

To whom it may concern:

This letter includes the catalogue numbers for VERACITY & VERACITY HC IVD KIT REAGENTS and VEGA software and accompanies the below EC Declaration of Conformity according to Annex III of 98/79/EC.

PRODUCT	CATALOGUE NUMBER
VERACITY IVD KIT REAGENTS (for up to 48 samples)	EV100-00-2048
VERACITY IVD KIT REAGENTS (for up to 96 samples)	EV101-00-2096
VERACITY HC IVD KIT REAGENTS (for up to 96 samples)	EV102-00-2096

Signed March 7, 2023, in Nicosia:

Professor Philippos C. Patsalis
Chief Executive Officer & Chief Medical Director
MEDICOVER GENETICS LIMITED

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
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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 ***VERACITY & VERACITY HC IVD KIT REAGENTS & VEGA software*** 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 *VERACITY & VERACITY HC IVD KIT REAGENTS & VEGA software* 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

NIPD GENETICS

EC DECLARATION OF CONFORMITY

According to Annex III of 98/79/EC

Manufacturer Name:	NIPD GENETICS MOLECULAR LABORATORIES LIMITED
Manufacturer Address:	31 Neas Engomis Str., 2409 Engomi, Nicosia, Cyprus
Name of Device(s):	VERACITY & VERACITY HC IVD KIT REAGENTS & VEGA Software
Category of IVD/Classification:	Other General IVD
Conformity Route:	Annex III of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Not part of List A or List B product, not for self-testing.
Standard applied:	ISO 13485:2016
Purpose of Device	Prenatal screening that analyses cell-free DNA from maternal plasma. Multiplex parallel analysis of specific regions of interest is applied for the copy number determination of chromosomes; risk of trisomy 13, 18 and upon request aneuploidies of X and Y, select microdeletions including DiGeorge (22q11.2 deletion), 1p36 deletion syndrome, Smith-Magenis (17p11.2 deletion), Wolf Hirschhorn (4p16.3 deletion) and Y detection. Combination of cell-free DNA from maternal plasma with paternal DNA sample from a buccal swap for the screening of monogenic diseases.

We hereby declare under our sole responsibility that the medical device(s) specified above meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices:

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.

2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
- availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

3. Undersigned declares to fulfill the obligations imposed by Annex IV, fully quality assurance system, sections 3 and 5:

- application for assessment for the quality system with a notified body as set in Annex IV (section 3) and application of the quality system ensures that the devices conform to the provisions of this Directive; and meets the requirements after audit by a notifying body as set in Annex IV (section 3).
- Quality system is in place based on the harmonized standard IS013485:2016, which has been certified by Lloyd's Register Quality Assurance Limited.
- the manufacturer authorizes the notifying body to carry out all necessary inspections and supply all the relevant information thus fulfilling the obligations imposed by the approved quality system as set under Annex IV (section 5).

4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I, Annex III and Annex IV have been met and documented.

The following (harmonized) standard(s) have been applied: European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

All supporting technical documentation is retained under the premises of the manufacturer and made available to the competent national authority, Cyprus Medical Devices Unit (Αρμόδια Αρχή Ιατροτεχνολογικού Εξοπλισμού).

Signed March 29, 2022 in Nicosia:

Professor Philippos Patsalis
Chief Executive Officer & Chief Medical Director
NIPD GENETICS PUBLIC COMPANY LIMITED
NIPD GENETICS MOLECULAR LABORATORIES LIMITED

NIPD GENETICS

EC DECLARATION OF CONFORMITY

According to Annex III of 98/79/EC

Manufacturer Name:	NIPD GENETICS MOLECULAR LABORATORIES LIMITED
Manufacturer Address:	31 Neas Engomis Str., 2409 Engomi, Nicosia, Cyprus
Name of Device(s):	VERACITY & VERACITY HC IVD KIT REAGENTS & VEGA Software
Name and ID of Notifying Body:	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (ID Number: 0318 *Risk of trisomy 21 determination)
Address of Notifying Body:	Campezo 1. Edificio 8, 28022 MADRID, Spain
Category of IVD/Classification:	IVDs in Annex II List B of the Directive
Conformity Route:	Annex IV Quality Assurance (ISO 13485:2016 by LLOYDS REGISTER QUALITY ASSURANCE LTD)

We hereby declare under our sole responsibility that the medical device(s) specified above meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices:

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.

2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
- availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

3. Undersigned declares to fulfill the obligations imposed by Annex IV, fully quality assurance system, sections 3 and 5:
- application for assessment for the quality system with a notified body as set in Annex IV (section 3) and application of the quality system ensures that the devices conform to the provisions of this Directive; and meets the requirements after audit by a notifying body as set in Annex IV (section 3).
- Quality system is in place based on the harmonized standard IS013485:2016, which has been certified by Lloyd's Register Quality Assurance Limited.
- the manufacturer authorizes the notifying body to carry out all necessary inspections and supply all the relevant information thus fulfilling the obligations imposed by the approved quality system as set under Annex IV (section 5).

4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I, Annex III and Annex IV have been met and documented.

The following (harmonized) standard(s) have been applied: European Directive 98/79/EC for in vitro Diagnostic Medical Devices.
Technical documentation demonstrating compliance is kept by the manufacturer and can be made available.

Signed March 29, 2022 in Nicosia:

Professor Philippos Patsalis
Chief Executive Officer & Chief Medical Director
NIPD GENETICS PUBLIC COMPANY LIMITED
NIPD GENETICS MOLECULAR LABORATORIES LIMITED