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):	TarCET PGT KIT
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	Next generation sequencing based kit intended for the pre-implantation genetic screening of whole chromosome aneuploidies and unbalanced structural rearrangements, of genomic material obtained following embryo biopsy, from *in-vitro* fertilized embryos.

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

1. Complies 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.

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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 April 18, 2022 in Nicosia:

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