EU Declaration of Conformity

Company name: Omixon Biocomputing Ltd.

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Omixon Biocomputing Ltd. (Kaposvár u. 14-18., Budapest, Hungary 1117) under its own exclusive responsibility hereby declares that the

- NanoTYPE 24/11 CE (*Reference number: NT2411CE*, GTIN: 5999565781279),
- NanoTYPE 96/11 CE (*Reference number: NT9611CE*, GTIN: 5999565781316) and
- NanoTYPE 4x96/11 CE (*Reference number: NT4x9611CE*, GTIN: 5999565781323)

device models of the device group NanoTYPE (Basic UDI-DI: 599956578001TV) conforms to the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL EU regulation.

Intended purpose:

Intended Use:		NanoTYPE is a family of qualitative in vitro diagnostic medical devices intended for the identification and definition of Class I (A, B, and C) and Class II (DQA1, DQB1, DRB1, DRB3/4/5, DPA1, DPB1) genes of the Human Leukocyte Antigens (HLA) complex from human genomic DNA derived from human whole blood. It is a single-use, non-automated assay utilizing polymerase chain reaction (PCR) to amplify a list of targeted genes depending on the product configuration. The generated amplicons are intended for a downstream library preparation and sequencing by Oxford Nanopore Technologies reagents and platforms in order to generate data for high resolution HLA genotyping using the Omixon NanoTYPER software. The assay results are intended to provide an HLA profile of the tested individual which can be used for example as an aid in assessment of the HLA gene compatibility between the patient and the donor population for the transplantation purposes.
Testing Population	Indication:	Transplantation patients and donors
	Limitation:	Not identified
	Contra-indication:	Heparin therapy

Intended Users:	NanoTYPE is intended for in vitro diagnostic use by professional healthcare personnel, such as laboratory technicians and physicians, trained in the techniques of molecular and in vitro diagnostic procedures as well as in HLA typing in diagnostic laboratories either EFI or ASHI accredited or able to work according to EFI or ASHI specifications.

Risk class of the device in accordance with the rules set out in Annex VIII: C

The products in the NanoTYPE device group has been CE marked according to *Annex IX CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION.*

Common specification:	Not available
Standards applied:	EN ISO 13485:2016+A11:2021
	EN ISO 14971:2019/A11:2021
	ISO 20916:2019
	ISO/TR 20416:2020
	EN ISO 15223-1:2021
	ISO 20417:2021
	ISO 23640:2015
	CLSI EP12-A2:2008 Correction Oct 2021

Notified Body Name: BSI Group The Netherlands B.V.
Address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands
Identification Number: 2797

Identification of the certificate: IVDR 747706

This Declaration of Conformity covers the NanoTYPE 24/11 CE, the NanoTYPE 96/11 CE, and the NanoTYPE 4x96/11 CE product belonging to this declaration.

Budapest 26/06/2024

Omixon Biocomputing Kft.
1117 Bp., Kaposvár utca 14-18.
Adószám: 23550070-2-43

Function: Managing Director

Name: Zoltán Simon

Signature: Simon