Summary of Safety and Performance

NanoTYPE Device Group

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Table of content

Revision and Change History

Version	Author	Summary of changes	Reviewed by Review date	Date of approval	Approved by
01	József Antal	First issue	Beatrix Kosiba 31/07/2023	31/07/2023	Elmar Schilling
02	József Antal	Correction made according to the NB review: introduction of the patient/lay person section, rephrasing Scientific Validity claims, abbreviation section introduced, correction of error in the NB name,	Gabriella Adlovits 30/11/2023	30/11/2023	Elmar Schilling
03	József Antal	Correction made following the NB review: correction to the title of the chapter on Scientific Validity, removal of redundant paragraph from Section A point 6.1, rephrasing Section B point 5.1	Gabriella Adlovits 12/02/2023	13/02/2023	Elmar Schilling
04	József Antal	Setting NB approval page, typo correction Basic UDI-ID	Gabriella Adlovits 03/06/2024	03/06/2024	Elmar Schilling
05	József Antal	Introduction new template for device family, new device group (family) members	Gabriella Adlovits 19/06/2024	19/06/2024	Elmar Schilling
06	Linda Komporday	Update of Intended use, intended users and method principle; addition of DNA isolation kits	Gabriella Adlovits Libor Kolesar Krisztina Rigó 22/05/2025	23/05/2025	Elmar Schilling 

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Location of controlled copy: Product Regulatory\01 - Technical Documentation Repository\02 - NanoTYPE\01 - NanoTYPE CE\Part G – Product V & V – Clinical performance and clinical evidence\					

This Summary of Safety and Performance (SSP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and performance of the device.

Section A. Summary of safety and performance for professional users

The following information is intended for professional users.
*Following this information there is a summary intended for patients/lay persons (please see **Section B**)*

The SSP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users.

Abbreviations

EUDAMED	European database on medical devices according to the IVDR (see below)
GTIN	Global Trade Item Number, serves as UDI-DI (see below)
IFU	Instructions for Use
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices
HLA	Human Leucocyte Antigen
KPL	Known Product Limitations
NGS	Next Generation Sequencing
ONT	Oxford Nanopore Technologies
PCR	Polymerase Chain Reaction
PMS	Post Market Surveillance
PMPF	Post-Market Performance Follow-Up
SSP	Summary of Safety and Performance
UDI	Unique Device Identification
UDI-DI	UDI device identifier ('UDI-DI') specific to a manufacturer and a device

1. Device Identification and General Information

1.1.	**Device Group Name**	NanoTYPE	**Trade name(s):** NanoTYPE 24/11 CE NanoTYPE 96/11 CE NanoTYPE 4x96/11 CE
1.2.	**Manufacturer**	**Name:**	Omixon Biocomputing Ltd.
		Address:	H-1117 Budapest, Kaposvár u. 14-18., Hungary, EU
1.3.		**SRN*:**	HU-MF-000003018
1.4.	**Device Basic UDI-DI:**		599956578001TV
1.5.	**EMDN****	**Code:**	W01030499
		Description:	TISSUE TYPING REAGENTS - OTHER
1.6.	**Risk class of device**		**C**
1.7.	**The device is neither for near-patient testing nor a companion diagnostic.**		
1.8.	**Year of the first IVDR certificate:**		2024
1.9.	**Authorised representative**	**Name:**	N/A
		SRN:	N/A
1.10.	**Notified Body**	**Name:**	BSI Group The Netherlands B.V.
		SIN*:**	2797

*: Single registration number. **: European Medical Device Nomenclature. ***: Single identification number

2. Intended Purpose

2.1.	**Intended use:**	The NanoTYPE device group includes 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. The members of the device group are single-use, non-automated assays utilizing polymerase chain reaction (PCR) to amplify a list of targeted genes depending on the device model. 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 as an aid in assessment of the HLA gene compatibility between the patient and the donor population for the transplantation purposes.
2.2.	**Patient**	**Population(s):**	Transplantation patients and donors
		Indications*:	N/A
2.3.		**Contra-indications**:**	Heparin therapy
2.4.	**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 HLA typing in diagnostic laboratories that operate in accordance with the industry best practice laboratory standards for HLA testing

3. Device Description

3.1. Description of the Device

3.1.1. Conditions to Use the Device

The device is for laboratory testing.

3.1.2. Method Principle

NanoTYPE 24/11 CE or 96/11 CE or 4x96/11 CE is an HLA amplification kit. The kit allows the simultaneous amplification of 11 HLA loci (HLA-A, B, C, DQA1, DQB1, DPA1, DPB1, DRB1, and DRB3/4/5) and provides workflow instructions for subsequent ONT library preparation and sequencing step as well as software analysis for HLA genotyping.
All 11 loci are amplified in a single, long-range multiplex PCR. In case of 1-3 samples, the amplicons are tagged with barcode(s), pooled and linked to an adapter. In case of ≥4 samples, there is an additional step - library size selection - between pooling and adapter attachment. The final library is then loaded into the flow cell.
During the sequencing, a DNA fragment enters a nanopore. As it goes through the nanopore, each DNA base disrupts the electrical field with a specific signature and can be used as a single molecule detector. The deconvolution of the electrical signal is done using a basecaller converting the electric signal into a DNA sequence with a FASTQ output format. This FASTQ file is then imported into NanoTYPER software for genotyping.

3.2. Description of the Device Kit(s)

Device Trade Name: NanoTYPE 24/11 CE for 24 reactions per kit

Component					Regulatory Status	Basic UDI-DI
ID	Name	Description	Filling Volume [µl]	Σ*		
A11	PCR Enzyme (24)	Thermostable DNA Polymerase enzyme	35	24	Accessory	N/A
A12	PCR Buffer (24)	Buffer	150	24	Accessory	N/A
A13	dNTP Mixture (24)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	60	24	Accessory	N/A
P206	HLA Multi Primer Mix 24/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA amplification / substrates of the PCR enzyme	22	24	Accessory	N/A

Device Trade Name: NanoTYPE 96/11 CE for 96 reactions per kit

Component					Regulatory Status	Basic UDI-DI
ID	Name	Description	Filling Volume [µl]	Σ*		
A14	PCR Enzyme (96)	Thermostable DNA Polymerase enzyme	140	96	Accessory	N/A
A15	PCR Buffer (96)	Buffer	600	96	Accessory	N/A

Component					Regulatory Status	Basic UDI-DI
ID	Name	Description	Filling Volume [µl]	Σ*		
A16	dNTP Mixture (96)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	240	96	Accessory	N/A
P208	HLA Multi Primer Mix 96/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA amplification / substrates of the PCR enzyme	90	96	Accessory	N/A

Device Trade Name: NanoTYPE 4x96/11 CE for 384 reactions per kit

Component (4 from each in this kit)					Regulatory Status	Basic UDI-DI
ID	Name	Description	Filling Volume [µl]	Σ*		
A14	PCR Enzyme (96)	Thermostable DNA Polymerase enzyme	140	96	Accessory	N/A
A15	PCR Buffer (96)	Buffer	600	96	Accessory	N/A
A16	dNTP Mixture (96)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	240	96	Accessory	N/A
P208	HLA Multi Primer Mix 96/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA	90	96	Accessory	N/A

Component (4 from each in this kit)					Regulatory Status	Basic UDI-DI
ID	Name	Description	Filling Volume [µl]	Σ*		
		amplification / substrates of the PCR enzyme				

*: Σ :No of reaction can be conducted

3.3. Previous Generation(s) or Variants of the Device

- NanoTYPE 24/11 RUO – Equivalent research use only product.
- NanoTYPE 24/11 CE – with HLA Multi Primer Mix 24/11 v2.0

3.4. Description of Any Accessories Which are Intended to Be Used in Combination with the Device

Other Devices:

Included:

NGS sequencer: Oxford Nanopore Technologies (ONT) MinION/GridION, specification is detailed in **Appendix C**

PCR Amplification: The NanoTYPE 24/11 CE was developed and validated on ABI Veriti 96-well thermocyclers with the following specification:

- PCR program used in an ABI 9600 emulation mode.

Liquid handling instruments:

- Micropipette capable of handling volumes of 1 to 1000 µL capacity,
- Multichannel pipette for handling volumes of 1-100 µL capacity.

DNA Quantitation: Qubit fluorometer (Thermo Fisher Scientific)

General laboratory equipment

- Magnetic stand for 1.5-2.0ml tubes
- 96-well cooler rack or ice bucket with ice
- 1.5ml tube cooler rack or ice bucket with ice
- Microplate centrifuge

			• Microtube centrifuge • Vortex • Timer
Other Articles:	**Excluded.**		Not identified.
	Included:	**NGS sequencing:**	• ONT MinION flow cell type R9.4.1 • ONT Rapid Barcoding Kit 96 (SQK-RBK110.96) • ONT Flow Cell Wash kit • MinKNOW software (sequencer's controlling software) specifications are detailed in **Appendix C**
		DNA Quantitation:	Qubit dsDNA BR Assay Kit •
		Consumables:	• Molecular grade ethanol • Molecular grade water (DNase and RNase free) • General laboratory consumables
	Excluded.		Not identified.

3.5. Description of Any Other Devices and Products Which are Intended to Be Used in Combination with the Device

Other Medical Devices:	**Included:**	NanoTYPER™ (HLA genotyping software)
	Excluded.	Not identified.

4. Reference to Any Harmonised Standards and CS Applied

4.1. Common Specifications (CS)

- Common Specification are not determined.

4.2. Harmonized Standards

- EN ISO 13485:2016+A11:2021 – Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

- EN ISO 14971:2019/A11:2021 – Medical devices - Application of risk management to medical devices (ISO 14971:2019)
- EN ISO 15223-1:2021 – Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

4.2.1. Other Standards

- ISO 20916:2019 – In vitro diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice
- ISO/TR 20416:2020 – Medical devices. Post-market surveillance for manufacturers
- ISO 23640:2015 – In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
- ISO 20417:2021 – Medical devices. Information to be supplied by the manufacturer
- CLSI EP12-A2:2008 Correction Oct 2021 User Protocol for Evaluation of Qualitative Test Performance

5. Risks and Warnings

5.1. Residual Risks and Undesirable Effects

- There is no unacceptable risk identified during Risk Management, however the Known Product Limitations of the devices are disclosed in **Section 5.3**.

5.2. Warnings And Precautions

5.2.1. Product safety

- The instructions in this document must be strictly and explicitly followed by qualified and properly trained personnel in order to ensure the proper and safe use of the product(s) described herein. All of the contents of this document must be fully read and understood prior to using such product(s).
- Failure to completely read and explicitly follow all of the instructions contained herein may result in damage to the product(s), injury to persons, including to users or others, and damage to other property. Omixon does not assume any liability arising out of the improper use of the product(s) described herein (including parts thereof or software) or any use of such product(s) outside the scope of the express written licenses or permissions granted by Omixon in connection with the customer's acquisition of such product(s).
- Good laboratory practice is essential for the proper execution of the test. Always separate pre and post-PCR steps in dedicated areas. Each workplace must be equipped with its own pipettes and the necessary auxiliary materials and equipment. Use only DNase-free consumables.
- When working with chemicals always wear: (1) suitable lab coat, (2) disposable gloves and (3) protective goggles.
- An overview of the chemical components of the device reagents can be found in the relevant SDSs uploaded to the Product support website. For other components, please consult the appropriate Safety Data Sheets (SDSs) available from the specified product suppliers.
- Avoid unnecessarily long exposure of reagents to a temperature out of the storing conditions.
- Do not expose reagents to UV light.
- Do not reconstitute or dilute the reagents in volumes other than described in this IFU. Do not use less than the specified volume of the reagents. These activities can lead to performance errors.
- Do not use the product if any of its components are damaged (broken vials, loose caps, etc.).
- Do not use the product past the expiry date indicated on the label!
- Do not substitute or mix device reagents with products from other manufacturers !
- Do not mix and match vials between kits. Vials from kits bearing different catalogue or LOT numbers can NOT be used interchangeably.
- It is strongly recommended to use different barcode sets for samples being processed in parallel for different sequencing runs and also for subsequent re-use of flow cells after washing.

- Keep track of the sample and its associated barcode throughout the process so that the sample can be always uniquely identified at each step of the protocol. The workbook is the recommended tool for this purpose.
- Keep track of the sample and its associated barcode throughout the process so that the sample can be always uniquely identified at each step of the protocol. The workbook is the recommended tool for this purpose.
- The user shall report any serious related to the device to the manufacturer and to the competent authority of the Member State where the user and/or the patient is located.
- It is the responsibility of the end user to use the protocol for a time-critical applications.

5.2.2. Reagent and sample handling

- We recommend isolating human gDNA from whole blood.
- Do not collect blood in heparinized tubes.
- Do not use lipemic or hemolyzed samples.
- Do no use blood samples from patients on heparin therapy.
- To ensure the quality and consistency of sample preparation, we recommend using a well-tested, commercially available DNA isolation kit.
- EDTA in gDNA elution buffer can inhibit PCR reaction, therefore it is recommended to use elution buffer with only low EDTA content.
- We recommend storing the prepared gDNA at -20°C or below for extended periods and avoid repetitive freeze/thawing of the gDNA to preserve its integrity and stability.
- When handling reagents or samples always wear: (1) an appropriate lab coat, (2) disposable gloves and (3) protective goggles.
- Dispose of used gloves in the hazardous waste container!
- Wash your hands thoroughly after removing gloves!
- Treat samples, materials and instruments as potentially infectious!
- Avoid microbial contamination of reagents when taking aliquots from reagent vials!
- Use disinfectant to clean and disinfect the areas used during the processing of samples!
- Use, storage and disposal of kit components and samples, should be in accordance with the procedures defined by national safety guidelines and in accordance with country, federal, state and local regulations.
- Use of this product should be limited to personnel trained in PCR, NGS techniques and NGS data analysis.
- Due to the sensitivity of the device, a care should be taken when handling samples and materials to ensure that reagents and their mixtures are not contaminated.
- Keep Barcode plate and RAP-F adapter reagents on ice until its use.
- Freezer temperature control and monitoring procedures must be in place and regularly maintained .

- It is always advisable to have sufficient supply of flow cells to avoid delays in sample processing due to low pore count flow cells.

5.2.3. Performance

- For the best performance, use the following in the same workflow: (1) NanoTYPE CE kit,(2) Omixon NanoTYPER™ CE software, and (3) the items in the Equipment, reagents, and supplies section.
- If other materials than the ones in the Equipment, reagents, and supplies section of the IFU are used, their verification and validation by the user is required.
- The recommended thermocycler is the ABI Veriti® or ABI VeritiPro® instrument. For ABI Veriti, set the ramp rate to be similar to the ABI 9600 emulation mode. For ABI VeritiPro, set the heating rate to +0.8°C/s and a cooling rate to -1.6°C/s.
- All instruments must be operated and maintained in accordance with good laboratory practice as defined by manufacturer's instructions and/or local laboratory rules (including calibration).
- For the best performance, the protocol requires 200 ng of gDNA per sample, the quality of which should correspond toh 260/280 absorbance values of 1.8-2.0 and 260/230 absorbance ratio values of 2.0-2.2. Values outside this range indicate impurities or the presence of contaminants (alcohol, salts, detergents, formaldehyde, heparin). It is important to accurately determine the input DNA concentration. We highly recommend the of a fluorometric method for accurate DNA quantification. Measuring DNA concentration by 260nm absorbance is not recommended.
  The integrity of a DNA sample must be preserved as the initial amplification step requires an appropriate amount of template material with more than 6.5 kilobases in length.
- If MinKNOW and NanoTYPER software are installed on the same computer do not perform basecalling and HLA genotyping at the same time, otherwise one of the processes may crash.
- The following reagents are known to be potential PCR inhibitors: EDTA, calcium, polysaccharide, isopropyl alcohol, ethanol, SDS, urea, guanidium salts and HOCl. If the concentrations of these substances in the gDNA samples exceed certain thresholds, the performance of the PCR will affected. Use an established DNA extraction method to remove these substances from your gDNA samples.
- RNA can be a potential PCR inhibitor of gDNA amplification. Use RNAse treatment during the DNA extraction to eliminate any traces of RNA.
- NanoTYPE was successfully tested in combination with some of the most commonly used extraction methods: 1) Chemagic DNA Blood KIT (CMG-1086-EFS) from Revvity, 2) QIAamp Blood Mini Kit (250) (51106) from Qiagen, 3) Maxwell RSC Whole Blood DNA Kit (AS1520) from Promega or 4) NucleoSpin Blood (740951.50) from Macherey-Nagel. . It is however user's

responsibility to always validate his extraction method in combination with the assay to exclude interference with unknown interfering substances.

- It is highly recommended to perform a reboot of the MinKNOW computer between the runs to preventively stabilize the operation system.

5.3. Other Relevant Aspects of Safety

The Known Product Limitations (KPL) document lists known ambiguities, assay and software limitations of the NanoTYPE product family. The KPL is bundled with the IFU and also available on the Omixon website under the MyOmixon > Product downloads > NanoTYPER, or can be requested from Omixon Support.

- In rare cases, unknown sequence variants that compromise primer binding may affect the amplification efficiency.

5.3.1. Ambiguities Due to Assay Design

Locus	Ambiguous allele group
HLA-DPB1	01:01:01/1484:01/1626:01Q/01:01:16
	02:01:02/1315:01/02:01:64
	04:01:01/1300:01/1321:01/1322:01/04:01:63/1436:01/1444:01Q/04:01:76/04:01:77
	04:02:01/1346:01
	05:01:01/1273:01/05:01:16
	13:01:01/107:01
	14:01:01/1653:01
	15:01:01/1499:01
	28:01:01/1654:01
	39:01:01/39:01:02
	105:01:01/1072:01/665:01:01
	296:01/1286:01
	584:01:01/584:01:02
HLA-DRB1	01:01:01/01:100/01:01:35/01:01:41/01:144
	03:01:01/03:01:31/03:147
	04:04:01/04:365
	04:06:02/04:354
	07:01:01/07:139/07:151
	08:01:01/08:105
	08:03:02/08:03:15
	09:01:02/09:31:02/09:57
	10:01:01/10:38
	11:01:01/11:01:50
	11:02:01/11:334
	12:01:01/12:10/12:111
	12:02:01/12:101/12:109

	13:01:01/13:01:34/13:01:42/13:361
	14:25:01/14:25:02
	14:54:01/14:216/14:243/14:253
	15:01:01/15:204
	15:02:01/15:140/15:149
	15:03:01/15:185
	16:02:01/16:64/16:75/16:76
HLA-DRB3	01:01:02/01:62:01/01:01:16/01:119/01:128
	02:02:01/02:144/02:167/02:168/02:188/02:189/02:193/02:02:34/02:02:35/02:204/02:211/02:212
	03:01:01/03:70/03:71
HLA-DRB4	01:01:01/01:156/01:168
	01:03:01/01:173
	01:03:01:02N/01:03:01:13N
HLA-DRB5	01:01:01/01:126/01:139

5.3.2. Assay Limitations

HLA-B*51:01:02:01, HLA-B*51:01:09, HLA-B*51:02:02, HLA-B*35:471, HLA-DQB1*03:276N and HLA-DRB4*03:01N are not amplified due to an indel at the forward primer site. The following allele groups may show low amplification, and very rarely (with a ~1% chance) allele dropouts may occur: HLA-DQB1*03, HLA-DQB1*04:02, HLA-DRB1*04, HLA-DRB1*07.

5.3.3. Ambiguities Due to the Limitations of the Sequencing Technology

Certain null and alternatively expressed alleles are not reported if a normally expressed allele match was found. The following well-documented null alleles are affected by this limitation, and the listed normally expressed alleles are reported:

- HLA-A*01:01:81/HLA-A*01:15N
- HLA-B*37:01:01/HLA-B*37:42N
- HLA-C*02:02:02/HLA-C*02:92N
- HLA-C*05:248/HLA-C*05:99N
- HLA-DRB1*07:01:01/HLA-DRB1*07:26N

5.3.4. Summary of Any Field Safety Corrective Action

- Not Applicable.

6. Summary of Performance Evaluation and Post-Market Performance Follow-Up (PMPF)

6.1. Summary of Scientific Validity of the Analyte

Based on the assessment of the available information, application of the human genomic DNA as an analyte is scientifically valid in both hematopoietic stem cell transplantation and solid organ transplantation with 11 loci determination and with low, intermediate, and high resolution for donor/recipient HLA matching. Venous blood as the claimed sample type is a scientifically valid source of human genomic DNA.

6.2. Summary of Performance Data from Equivalent Device(s)

Not Applicable.

6.3. Summary of Performance Data from Studies Conducted Prior to CE-Marking

Analytical Performance	**Trueness:**		99.50 %	
	Repeatability:		100.0 %	
	Reproducibility:	**Lot-to-Lot:**	99.73 %	
		Operator-to-Operator:	100.0 %	
		Equivalency of sample setups:	multi vs. single:	99.8 %
			12 vs. 4:	100.0 %
			12 vs. 24:	100.0 %
	Accuracy:		99.96 %	
Stability	**In-use Open:**		>6 hours	
	In-use Closed:		>6 hours	
	Shelf life:		24 months	
	Transport stability:		No deterioration and leakage under the defined shipping condition.	
Interference	**DNA Isolation kits**		Will be determined in a PMPF Study	
	Interfering substances: may cause interference above given concentration limit		• EDTA above 0.5 mM • Calcium above 2.0 mM • Polysaccharide above 60.0 ng/µL • Isopropyl alcohol above 1% (v/v) • Ethanol above 1% (v/v) • SDS above 1% (v/v) • Urea above 0.005% (w/v) • Guanidium salts above 20 mM • HOCl above 100 µM	
Clinical Performance	**Positive Percentage Agreement:**		99.44%	
	Negative Percentage Agreement:		99.98%	
Technical Features	**Total amplification time:**		<3 hours	
	Amplicon concentration	**Routine protocol:**	>37 ng/µl	
		Single protocol:	>37 ng/µl	

6.3.1. Locus Level Clinical Performance Parameters

6.3.1.1. Positive Percentage Agreement

Locus	Routine and single protocols [%]	Single sample protocol [%]
HLA-A	100.0	100.0
HLA-B	99.61	100.0
HLA-C	100.0	100.0
HLA-DPA1	100.0	100.0
HLA-DPB1	100.0	100.0
HLA-DQA1	99.48	97.73
HLA-DQB1	98.03	97.73
HLA-DRB1	99.74	100.0
HLA-DRB3	98.82	100.0
HLA-DRB4	98.56	95.45
HLA-DRB5	99.61	100.0
Cumulative PPA	99.44	99.90

6.3.1.2. Negative Percentage Agreement

Locus	Routine and single protocols [%]	Single sample protocol [%]
HLA-A	100.0	100.0
HLA-B	99.99	100.0
HLA-C	100.0	100.0
HLA-DPA1	100.0	100.0
HLA-DPB1	100.0	100.0
HLA-DQA1	99.98	99.77
HLA-DQB1	99.91	99.77
HLA-DRB1	99.99	100.0
HLA-DRB3	99.83	100.0
HLA-DRB4	99.64	97.73
HLA-DRB5	99.90	100.0
Cumulative PPA	99.98	99.90

6.3.1.3. Locus Level Analytical Performance Parameters

Locus	Trueness [%]	Accuracy [%]	Precision [%]					
			Repeatability	Reproducibility				
				Lot-to-Lot	Operator-to-Operator	Equivalency of sample setups		
						Multi-Sample vs. Single-Sample	12 Sample vs. 24 Sample	12 Sample vs. 4 Sample
HLA-A	99.48	99.98	100.0	100.00	100.0	100.0	100.0	100.0
HLA-B	99.48	99.98	100.0	100.00	100.0	100.0	100.0	100.0
HLA-C	99.74	99.98	100.0	100.00	100.0	100.0	100.0	100.0
HLA-DPA1	99.47	99.90	100.0	100.00	100.0	98.1	98.1	98.1
HLA-DPB1	99.22	99.94	100.0	99.60	100.0	100.0	100.0	100.0
HLA-DQA1	98.95	98.88	100.0	98.77	100.0	100.0	100.0	100.0
HLA-DQB1	99.22	99.91	100.0	100.00	100.0	100.0	100.0	100.0
HLA-DRB1	99.74	99.99	100.0	100.00	100.0	100.0	100.0	100.0
HLA-DRB3	99.21	99.74	100.0	98.73	100.0	100.0	100.0	100.0
HLA-DRB4	100.00	100.00	100.0	100.00	100.0	100.0	100.0	100.0
HLA-DRB5	100.00	100.00	100.0	100.00	100.0	100.0	100.0	100.0
Cumulative	99.50	99.96	100.0	99.73	100.0	100.0	100.0	100.0

6.4. Summary of Performance Data from Other Sources

Not Applicable.

6.5. Overall Summary of the Performance and Safety

According to the **Analytical Performance** of the Omixon NanoTYPE CE, the products of the NanoTYPE device group fulfilled the **Design Verification** requirements.
The **Clinical Performance** of Omixon NanoTYPE CE was determined with all **Clinical Performance parameters** and **Technical Features** defined in the objectives of the Studies, and the **Scientific Validity** was demonstrated.
According to the **Performance Evaluation** the Omixon NanoTYPE CE is

- compliant with the relevant general safety and performance requirements with respect to clinical performance,
- safe and effective for its intended use.

6.6. Ongoing or Planned Post-Market Performance Follow-Up

According to the PMSP-NT2411CE-001 *PMSP for NanoTYPE 24_11* CE_v5 ***Post Market Surveillance Plan*** of the Device the following **Post-Market Performance Follow-Up** activities are planned for assessing direct information about safety and performance of the device:

- *PMPFP- NT2411CE-001 PMPFP for NanoTYPE 24_11 CE_v5.pdf*, including
    - PMPF Study on the failure rate of ONT flow cells.
    - PMPF Study on the device performance after IMGT database update as determined in Study Plan: IMGT/HLA 0.00.0 study design Confluence page: https://confluence.omixon.com/pages/viewpage.action?pageId=105055392
    - PMPF Study aiming at the evaluation of the performance of different commercially available DNA isolating kits
    - PMPF study aiming at MinKNOW software updates.
    - PMPF Study aiming at the stability evaluation of the new device models.

7. Metrological Traceability of Assigned Values

7.1. Explanation of the Unit of Measurement

Not Applicable.

7.2. Applied Reference Materials and/or Reference Measurement Procedures Used for Calibration

- Reference Material / Calibrator is Not Applicable.
- Reference Method is Not Applicable.

8. Suggested Profile and Training for Users

Profile is Not Applicable.
Training with predefined training material is available in connection with the required training of the NanoTYPER IVD Medical Device Software as NanoTYPE CE training presentation.

Section B. Summary of safety and performance for patients/lay persons

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the device not intended for self-testing. The information presented below is intended for patients or lay persons. A more extensive summary of the safety and performance prepared for healthcare professionals is found in the first part of this document, ***Section A****.*

The SSP is not intended to give general advice on the diagnosis and/or treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.
The SSP is not intended to replace the Instructions For Use to provide information on the safe use of the device.

Abbreviations

EUDAMED	European database on medical devices according to the IVDR (see below)
GTIN	Global Trade Item Number, serves as UDI-DI (see below)
IFU	Instructions for Use
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices
HLA	Human Leucocyte Antigen
KPL	Known Product Limitations
NGS	Next Generation Sequencing
ONT	Oxford Nanopore Technologies
PCR	Polymerase Chain Reaction
PMS	Post Market Surveillance
PMPF	Post-Market Performance Follow-Up
SSP	Summary of Safety and Performance
UDI	Unique Device Identification
UDI-DI	UDI device identifier ('UDI-DI') specific to a manufacturer and a device

1. Device identification and general information

			Trade name(s):
1.1.	**Device Group Name**	**NanoTYPE**	NanoTYPE 24/11 CE NanoTYPE 96/11 CE NanoTYPE 4x96/11 CE
1.2.	**Manufacturer**	**Name:**	Omixon Biocomputing Ltd.
		Address:	H-1117 Budapest, Kaposvár u. 14-18., Hungary, EU
1.3.	**Device Basic UDI-DI:**		599956578001TV
1.4.	**Risk class of device**		**C**
1.5.	**Year of the first IVDR certificate:**		N/A

2. Intended Purpose

2.1.	**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 as an aid in assessment of the HLA gene compatibility between the patient and the donor population for the transplantation purposes.

2.2.	**Patient**	**Population(s):**	Transplantation patients and donors
		Indications*:	N/A
2.3.		**Contra-indications**:**	Heparin therapy
2.4.	**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.

3. Device Description

3.1. General Description of the Device

The device is for laboratory testing.

3.2. How The Device is Achieving its Intended Purpose

NanoTYPE 24/11 or 96/11 or 4x96/11 is an HLA amplification kit. The kit allows the simultaneous amplification of 11 HLA loci (HLA-A, B, C, DQA1, DQB1, DPA1, DPB1, DRB1, and DRB3/4/5) and provides workflow instructions for subsequent ONT library preparation and sequencing step as well as software analysis for HLA genotyping.
All 11 loci are amplified in a single, long-range multiplex PCR. In case of 1-3 samples, the amplicons are tagged with barcode(s), pooled and linked to an adapter. In case of ≥4 samples, there is an additional step - library size selection - between pooling and adapter attachment. The final library is then loaded into the flow cell.
During the sequencing, a DNA fragment enters a nanopore. As it goes through the nanopore, each DNA base disrupts the electrical field with a specific signature and can be used as a single molecule detector. The deconvolution of the electrical signal is done using a basecaller converting the electric signal into a DNA sequence with a FASTQ output format. This FASTQ file is then imported into NanoTYPER software for genotyping.

3.3. Description of the Kit(s)

Device Trade Name: NanoTYPE 24/11 CE for 24 reactions per kit

Component				Regulatory Status	Basic UDI-DI
ID	Name	Description	No of Reactions		
A11	PCR Enzyme (24)	Thermostable DNA Polymerase enzyme	24	Accessory	N/A
A12	PCR Buffer (24)	Buffer	24	Accessory	N/A
A13	dNTP Mixture (24)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	24	Accessory	N/A
P206	HLA Multi Primer Mix 24/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA amplification / substrates of the PCR enzyme	24	Accessory	N/A

Device Trade Name: NanoTYPE 96/11 CE for 96 reactions per kit

Component				Regulatory Status	Basic UDI-DI
ID	Name	Description	No of Reactions		
A14	PCR Enzyme (96)	Thermostable DNA Polymerase enzyme	96	Accessory	N/A
A15	PCR Buffer (96)	Buffer	96	Accessory	N/A

Component				Regulatory Status	Basic UDI-DI
ID	Name	Description	No of Reactions		
A16	dNTP Mixture (96)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	96	Accessory	N/A
P208	HLA Multi Primer Mix 96/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA amplification / substrates of the PCR enzyme	96	Accessory	N/A

Device Trade Name: NanoTYPE 4x96/11 CE for 384 reactions per kit

Component (4 from each in this kit)				Regulatory Status	Basic UDI-DI
ID	Name	Description	No of Reactions		
A14	PCR Enzyme (96)	Thermostable DNA Polymerase enzyme	96	Accessory	N/A
A15	PCR Buffer (96)	Buffer	96	Accessory	N/A
A16	dNTP Mixture (96)	Mixture of monomer molecule for DNA amplification / substrates of the PCR enzyme	96	Accessory	N/A
P208	HLA Multi Primer Mix 96/11 v2.1	Primer mixture / mixture of highly selective short DNA sequences for starting DNA amplification / substrates of the PCR enzyme	96	Accessory	N/A

3.4. Description of Any Accessories Which are Intended to Be Used in Combination with the Device

Other Devices:	**Included:**	**NGS sequencer:**	Oxford Nanopore Technologies (ONT) MinION/GridION, specification is detailed in Appendix C
		PCR Amplification:	The NanoTYPE 24/11 CE was developed and validated on ABI Veriti 96-well thermocyclers with the following specification: PCR program used in an ABI 9600 emulation mode.
		Liquid handling instruments:	Micropipette capable of handling volumes of 1 to 1000 µL capacity, Multichannel pipette for handling volumes of 1-100 µL capacity.
		DNA Quantitation:	Qubit fluorometer (Thermo Fisher Scientific)
		General laboratory equipment	Magnetic stand for 1.5-2.0ml tubes 96-well cooler rack or ice bucket with ice 1.5ml tube cooler rack or ice bucket with ice Microplate centrifuge Microtube centrifuge Vortex Timer
	Excluded:		Not identified.
Other Articles:	**Included:**	**NGS sequencing:**	ONT MinION flow cell type R9.4.1 ONT Rapid Barcoding Kit 96 (SQK-RBK110.96) ONT Flow Cell Wash kit MinKNOW software (sequencer's controlling software) specifications are detailed in Appendix C
		DNA Quantitation:	Qubit dsDNA BR Assay Kit
		Consumables:	Molecular grade ethanol Molecular grade water (DNase and RNase free) General laboratory consumables
	Excluded:		Not identified.

3.5. Description of Any Other Devices and Products Which are Intended to Be Used in Combination with the Device

Other Medical Devices:	**Included:**	NanoTYPER™ (HLA genotyping software)
	Excluded.	Not identified.

4. Risks and Warnings

Contact your healthcare professional if you are concerned about the use of the device or about the results.
This document is not intended to replace a consultation with your healthcare professional, if needed.

4.1. How Potential Risks Have Been Controlled or Managed

Omixon Ltd. applies a procedure integrated into the company's quality management system to control risk management. Risk management is performed to evaluate

- the safety of the IVD Medical Devices related to the patient, the user and other persons and
- the impacts of proposed changes to both processes and products to such safety.

Risk management encompasses risk analysis, risk evaluation, risk control during Design and Development, production and post market activities throughout the life cycle of an IVD product.
As for all IVD medical Devices produced by Omixon Ltd. a risk management file containing the records of the risk management related to all identified risks is established and maintained for the NanoTYPE device.
Omixon eliminates or reduces risks as far as possible without adversely affecting the benefit-risk ratio and make all efforts to keep any residual risk as low as possible. Any remaining risks will be weighed against the benefits that the product has for the patient.
Omixon will inform the user or other persons of any residual risks in the IFU and/or KPL.

4.2. Residual Risks and Undesirable Effects

- There is no unacceptable risk identified during Risk Management, however the Known Product Limitations of the devices are disclosed in **Section 4.4**.

4.3. Warnings And Precautions

4.3.1. Product safety

- The instructions in this document must be strictly and explicitly followed by qualified and properly trained personnel in order to ensure the proper and safe use of the product(s) described herein. All of the contents of this document must be fully read and understood prior to using such product(s).

- Failure to completely read and explicitly follow all of the instructions contained herein may result in damage to the product(s), injury to persons, including to users or others, and damage to other property. Omixon does not assume any liability arising out of the improper use of the product(s) described herein (including parts thereof or software) or any use of such product(s) outside the scope of the express written licenses or permissions granted by Omixon in connection with the customer's acquisition of such product(s).
- Good laboratory practice is essential for the proper execution of the test. Always separate pre and post-PCR steps in dedicated areas. Each workplace must be equipped with its own pipettes and the necessary auxiliary materials and equipment. Use only DNase-free consumables.
- When working with chemicals always wear: (1) suitable lab coat, (2) disposable gloves and (3) protective goggles.
- An overview of the chemical components of the device reagents can be found in the relevant SDSs uploaded to the Product support website. For other components, please consult the appropriate Safety Data Sheets (SDSs) available from the specified product suppliers.
- Avoid unnecessarily long exposure of reagents to a temperature out of the storing conditions.
- Do not expose reagents to UV light.
- Do not reconstitute or dilute the reagents in volumes other than described in this IFU. Do not use less than the specified volume of the reagents. These activities can lead to performance errors.
- Do not use the product if any of its components are damaged (broken vials, loose caps, etc.).
- Do not use the product past the expiry date indicated on the label!
- Do not substitute or mix device reagents with products from other manufacturers !
- Do not mix and match vials between kits. Vials from kits bearing different catalogue or LOT numbers can NOT be used interchangeably.
- It is strongly recommended to use different barcode sets for samples being processed in parallel for different sequencing runs and also for subsequent re-use of flow cells after washing.
- Keep track of the sample and its associated barcode throughout the process so that the sample can be always uniquely identified at each step of the protocol. The workbook is the recommended tool for this purpose.
- Keep track of the sample and its associated barcode throughout the process so that the sample can be always uniquely identified at each step of the protocol. The workbook is the recommended tool for this purpose.

- The user shall report any serious related to the device to the manufacturer and to the competent authority of the Member State where the user and/or the patient is located.
- It is the responsibility of the end user to use the protocol for a time-critical applications.

4.3.2. Reagent and sample handling

- We recommend isolating human gDNA from whole blood.
- Do not collect blood in heparinized tubes.
- Do not use lipemic or hemolyzed samples.
- Do no use blood samples from patients on heparin therapy.
- To ensure the quality and consistency of sample preparation, we recommend using a well-tested, commercially available DNA isolation kit.
- EDTA in gDNA elution buffer can inhibit PCR reaction, therefore it is recommended to use elution buffer with only low EDTA content.
- We recommend storing the prepared gDNA at -20°C or below for extended periods and avoid repetitive freeze/thawing of the gDNA to preserve its integrity and stability.
- When handling reagents or samples always wear: (1) an appropriate lab coat, (2) disposable gloves and (3) protective goggles.
- Dispose of used gloves in the hazardous waste container!
- Wash your hands thoroughly after removing gloves!
- Treat samples, materials and instruments as potentially infectious!
- Avoid microbial contamination of reagents when taking aliquots from reagent vials!
- Use disinfectant to clean and disinfect the areas used during the processing of samples!
- Use, storage and disposal of kit components and samples, should be in accordance with the procedures defined by national safety guidelines and in accordance with country, federal, state and local regulations.
- Use of this product should be limited to personnel trained in PCR, NGS techniques and NGS data analysis.
- Due to the sensitivity of the device, a care should be taken when handling samples and materials to ensure that reagents and their mixtures are not contaminated.
- Keep Barcode plate and RAP-F adapter reagents on ice until its use.
- Freezer temperature control and monitoring procedures must be in place and regularly maintained .
- It is always advisable to have sufficient supply of flow cells to avoid delays in sample processing due to low pore count flow cells.

    - Assay Limitations

HLA-B*51:01:02:01, HLA-B*51:01:09, HLA-B*51:02:02, HLA-B*35:471, HLA-DQB1*03:276N and HLA-DRB4*03:01N are not amplified due to an indel at the forward primer site. The following

allele groups may show low amplification, and very rarely (with a ~1% chance) allele dropouts may occur: HLA-DQB1*03, HLA-DQB1*04:02, HLA-DRB1*04, HLA-DRB1*07.

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4.3.3. Performance

- For the best performance, use the following in the same workflow: (1) NanoTYPE CE kit,(2) Omixon NanoTYPER™ CE software, and (3) the items in the Equipment, reagents, and supplies section.
- If other materials than the ones in the Equipment, reagents, and supplies section of the IFU are used, their verification and validation by the user is required.
- The recommended thermocycler is the ABI Veriti® or ABI VeritiPro® instrument. For ABI Veriti, set the ramp rate to be similar to the ABI 9600 emulation mode. For ABI VeritiPro, set the heating rate to +0.8°C/s and a cooling rate to -1.6°C/s.
- All instruments must be operated and maintained in accordance with good laboratory practice as defined by manufacturer's instructions and/or local laboratory rules (including calibration).
- For the best performance, the protocol requires 200 ng of gDNA per sample, the quality of which should correspond toh 260/280 absorbance values of 1.8-2.0 and 260/230 absorbance ratio values of 2.0-2.2. Values outside this range indicate impurities or the presence of contaminants (alcohol, salts, detergents, formaldehyde, heparin). It is important to accurately determine the input DNA concentration. We highly recommend the of a fluorometric method for accurate DNA quantification. Measuring DNA concentration by 260nm absorbance is not recommended.
- The integrity of a DNA sample must be preserved as the initial amplification step requires an appropriate amount of template material with more than 6.5 kilobases in length.
- If MinKNOW and NanoTYPER software are installed on the same computer do not perform basecalling and HLA genotyping at the same time, otherwise one of the processes may crash.
- The following reagents are known to be potential PCR inhibitors: EDTA, calcium, polysaccharide, isopropyl alcohol, ethanol, SDS, urea, guanidium salts and HOCl. If the concentrations of these substances in the gDNA samples exceed certain thresholds, the performance of the PCR will affected. Use an established DNA extraction method to remove these substances from your gDNA samples.
- RNA can be a potential PCR inhibitor of gDNA amplification. Use RNAse treatment during the DNA extraction to eliminate any traces of RNA.
- NanoTYPE was successfully tested in combination with some of the most commonly used extraction methods: 1) Chemagic DNA Blood KIT (CMG-1086-EFS) from Revvity, 2) QIAamp Blood Mini Kit (250) (51106) from Qiagen, 3) Maxwell RSC Whole Blood DNA Kit (AS1520) from

Promega or 4) NucleoSpin Blood (740951.50) from Macherey-Nagel. . It is however user's responsibility to always validate his extraction method in combination with the assay to exclude interference with unknown interfering substances.

- It is highly recommended to perform a reboot of the MinKNOW computer between the runs to preventively stabilize the operation system.

4.4. Other Relevant Aspects of Safety

Refer to the Known Product Limitations (KPL) document for known ambiguities, assay and software limitations of the NanoTYPE product family. The KPL is bundled with the IFU and also available on the Omixon website under the MyOmixon > Product downloads > NanoTYPER, or can be requested from Omixon Support.

4.4.1. Ambiguities Due to Assay Design

Locus	Ambiguous allele group
HLA-DPB1	01:01:01/1484:01/1626:01Q/01:01:16
	02:01:02/1315:01/02:01:64
	04:01:01/1300:01/1321:01/1322:01/04:01:63/1436:01/1444:01Q/04:01:76/04:01:77
	04:02:01/1346:01
	05:01:01/1273:01/05:01:16
	13:01:01/107:01
	14:01:01/1653:01
	15:01:01/1499:01
	28:01:01/1654:01
	39:01:01/39:01:02
	105:01:01/1072:01/665:01:01
	296:01/1286:01
	584:01:01/584:01:02
HLA-DRB1	01:01:01/01:100/01:01:35/01:01:41/01:144
	03:01:01/03:01:31/03:147
	04:04:01/04:365
	04:06:02/04:354

	07:01:01/07:139/07:151
	08:01:01/08:105
	08:03:02/08:03:15
	09:01:02/09:31:02/09:57
	10:01:01/10:38
	11:01:01/11:01:50
	11:02:01/11:334
	12:01:01/12:10/12:111
	12:02:01/12:101/12:109
	13:01:01/13:01:34/13:01:42/13:361
	14:25:01/14:25:02
	14:54:01/14:216/14:243/14:253
	15:01:01/15:204
	15:02:01/15:140/15:149
	15:03:01/15:185
	16:02:01/16:64/16:75/16:76
HLA-DRB3	01:01:02/01:62:01/01:01:16/01:119/01:128
	02:02:01/02:144/02:167/02:168/02:188/02:189/02:193/02:02:34/02:02:35/02:204/02:211/02:212
	03:01:01/03:70/03:71
HLA-DRB4	01:01:01/01:156/01:168
	01:03:01/01:173
	01:03:01:02N/01:03:01:13N
HLA-DRB5	01:01:01/01:126/01:139

4.4.2. Assay Limitations

HLA-B*51:01:02:01, HLA-B*51:01:09, HLA-B*51:02:02, HLA-B*35:471, HLA-DQB1*03:276N and HLA-DRB4*03:01N are not amplified due to an indel at the forward primer site. The following allele groups may show low amplification, and very rarely (with a ~1% chance) allele dropouts may occur: HLA-DQB1*03, HLA-DQB1*04:02, HLA-DRB1*04, HLA-DRB1*07.

HLA-DQB1*03:276N and HLA-DRB4*03:01N are not amplified due to the deletion of the forward primer site. The following allele groups may show low amplification, and very rarely (with a ~1% chance) allele dropouts may occur: HLA-DQB1*03:01, HLA-DQB1*03:03, HLA-DQB1*04:02, HLA-DRB1*04, HLA-DRB1*07:01.

4.4.3. Ambiguities Due to The Limitations of the Sequencing Technology

Certain null and alternatively expressed alleles are not reported if a normally expressed allele match was found. The following well-documented null alleles are affected by this limitation, and the listed normally expressed alleles are reported:

- HLA-A*01:01:81/HLA-A*01:15N
- HLA-B*37:01:01/HLA-B*37:42N
- HLA-C*02:02:02/HLA-C*02:92N
- HLA-C*05:248/HLA-C*05:99N
- HLA-DRB1*07:01:01/HLA-DRB1*07:26N

4.5. Summary of Any Field Safety Corrective Action

- Not Applicable.

5. Summary of Performance Evaluation and Post-Market Performance Follow-Up (PMPF)

5.1. Summary of Scientific Validity of the Analyte

When matching donors and recipients for transplants, we check if their genes match up well. Clinicians used information about persons DNA, measured by NanoTYPE CE, to confirm it's a good method for both bone marrow and organ transplants like kidney or heart. It helps figure out if they are a good match for 11 specific genes. This method can tell us how well they match with three levels of accuracy – low, medium, or high. They used blood samples, which works well for this.

5.2. Overall Summary of the Performance and Safety

According to the **Analytical Performance** of the Omixon NanoTYPE CE, the the products of the NanoTYPE device group fulfilled the **Design Verification** requirements.
The **Clinical Performance** of Omixon NanoTYPE CE was determined with all **Clinical Performance parameters** and **Technical Features** defined in the objectives of the Studies, and the **Scientific Validity** was demonstrated.
According to the **Performance Evaluation** the Omixon NanoTYPE CE is

- compliant with the relevant general safety and performance requirements with respect to clinical performance,
- safe and effective for its intended use.

5.3. Summary of Performance Data from Studies Conducted Prior to CE-Marking

Analytical Performance	**Trueness:**		99.50 %	
	Repeatability:		100.0 %	
	Reproducibility:	**Lot-to-Lot:**	99.73 %	
		Operator-to-Operator:	100.0 %	
		Equivalency of sample setups:	multi vs. single:	99.8 %
			12 vs. 4:	100.0 %
			12 vs. 24:	100.0 %
	Accuracy:		99.96 %	
Stability	**In-use Open:**		>6 hours	
	In-use Closed:		>6 hours	
	Shelf life:		24 months	

	Transport stability:	No deterioration and leakage under the defined shipping condition.
Interference	**DNA Isolation kits:**	• Chemagic DNA Blood KIT (CMG-1086-EFS) from Revity • QIAamp Blood Mini Kit (250) (51106) from Qiagen • Maxwell RSC Whole Blood DNA Kit (AS1520) from Promega • NucleoSpin Blood (740951.50) from Macherey-Nagel
	Interfering substances: may cause interference above given concentration limit	• EDTA above 0.5 mM • Calcium above 2.0 mM • Polysaccharide above 60.0 ng/µL • Isopropyl alcohol above 1% (v/v) • Ethanol above 1% (v/v) • SDS above 1% (v/v) • Urea above 0.005% (w/v) • Guanidium salts above 20 mM • HOCl above 100 µM
Clinical Performance	**Positive Percentage Agreement:**	99.44%
	Negative Percentage Agreement:	99.98%
Technical Features	**Total amplification time:**	<3 hours
	Amplicon concentration **Routine protocol:**	>37 ng/µl
	Single protocol:	>37 ng/µl

5.4. Summary of Performance Data from Equivalent Device(s) and/ or Other Sources

Not Applicable.

5.5. Ongoing or Planned Post-Market Performance Follow-Up

According to the ***Post Market Surveillance Plan*** of the Device the following **Post-Market Performance Follow-Up Studies** are planned for assessing direct information about safety and performance of the NanoTYPE CE:

- PMPF Study on the failure rate of ONT flow cells.
    - PMPF Study on the device performance after IMGT database update.
    - PMPF Study aiming at the evaluation of the performance of different commercially available DNA isolating kits

- PMPF study aiming at MinKNOW software updates.
- PMPF Study aiming at the stability evaluation of the new device models.

6. Suggested Profile and Training for Users

Profile is Not Applicable.
Training with predefined training material is available in connection with the required training of the models of the NanoTYPE device group as NanoTYPE CE training presentation.

Revision History by NB

SSP			Validated by NB	
Revision No.	Issue Date	Change	Yes / validation language	No*
01	25/03/2024	First Issue	☒ English	☐
06	23/05/2025	Updated with changes related to change request CRF-2025-001 s	☐	☒

*: only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB). Checked symbol: X, unchecked symbol: ☐