EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 694131**

Issued To: **Omixon Biocomputing Ltd.**
Kaposvár u. 14-18
Budapest
1117
Hungary

In respect of:

Design and manufacture of HLA typing assays to detect HLA-DR, HLA-A and HLA-B tissue types by utilizing NGS technology.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2018-12-18** Date: **2022-05-23** Expiry Date: **2025-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 694131

Issued To:

Omixon Biocomputing Ltd.
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Number	Device Name	Intended purpose IFU
Annex II List B		
IVD0306	**11-locus devices**	
	Holotype HLA 96/11 Configuration A & CE v2 (REF H72)	The Holotype HLA 96/11 – Configurations are in-vitro diagnostic assay reagents which are intended to be used in combination with Omixon HLA TWIN CE certified IVD software for the identification and definition of Class I and II Human Leukocyte Antigens (HLA) and is for use in HLA typing utilizing the Illumina® MiSeq and MiniSeq Next Generation Sequencing platforms. The Holotype HLA provides human histocompatibility information of HLA Class I (A, B, and C) and Class II (DPA1, DPB1, DQA1, DQB1, DRB1, DRB3, DRB4 and DRB5) loci using human genomic DNA.
	Holotype HLA 96/11 Configuration B & CE v2 (REF H76)	
	Holotype HLA 96/11 Configuration C & CE v2 (REF: H78)	
IVD0306	Holotype HLA 24/11 Configuration A1 & CE v2 (REF: H62)	The Holotype HLA 24/11 –Configurations are in-vitro diagnostic assay reagents which are intended to be used in combination with Omixon HLA TWIN CE certified IVD software for the identification and definition of Class I and II Human Leukocyte Antigens (HLA) and is for use in HLA typing utilizing the Illumina® MiSeq and MiniSeq Next Generation Sequencing platforms. The Holotype HLA provides human histocompatibility information of HLA Class I (A, B, and C) and Class II (DPA1, DPB1, DQA1, DQB1, DRB1, DRB3, DRB4 and DRB5) loci using human genomic DNA.
	Holotype HLA 24/11 Configuration A2 & CE v2 (REF: H64)	
	Holotype HLA 24/11 Configuration A3 & CE v2 (REF: H66)	
	Holotype HLA 24/11 Configuration A4 & CE v2 (REF: H68)	

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Number	Device Name	Intended purpose IFU
Annex II List B		
IVD 0306	**7- locus devices**	
	Holotype HLA 96/7 Configuration A & CE v2 (REF: H32.1)	The Holotype HLA 96/7 – Configurations are in-vitro diagnostic assay reagents which are intended to be used in combination with Omixon HLA TWIN CE certified IVD software for the identification and definition of Class I and II Human Leukocyte Antigens (HLA) and is for use in HLA typing utilizing the Illumina® MiSeq and MiniSeq Next Generation Sequencing platforms. The Holotype HLA provides human histocompatibility information of HLA Class I (A, B, and C) and Class II (DPB1, DQA1, DQB1 and DRB1) loci using human genomic DNA.
	Holotype HLA 96/7 Configuration B & CE v2 (REF: H34.1)	
	Holotype HLA 96/7 Configuration C & CE v2 (REF: H38)	
IVD 0306	Holotype HLA 24/7 Configuration A1 & CE v2 (REF: H52.1)	The Holotype HLA 24/7 – Configurations are in-vitro diagnostic assay reagents which are intended to be used in combination with Omixon HLA TWIN CE certified IVD software for the identification and definition of Class I and II Human Leukocyte Antigens (HLA) and is for use in HLA typing utilizing the Illumina® MiSeq and MiniSeq Next Generation Sequencing platforms. The Holotype HLA provides human histocompatibility information of HLA Class I (A, B, and C) and Class II (DPB1, DQA1, DQB1 and DRB1) loci using human genomic DNA.
	Holotype HLA 24/7 Configuration A2 & CE v2 (REF: H56)	
	Holotype HLA 24/7 Configuration A3 & CE v2 (REF: H58)	
	Holotype HLA 24/7 Configuration A4 & CE v2 (REF: H60)	

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Number	Device Name	Intended purpose IFU
Annex II List B		
IVD 0306	**5-locus devices**	
	Holotype HLA 96/5 Configuration A & CE v2 (REF: H23)	The Holotype HLA 96/5 – Configurations are in-vitro diagnostic assay reagents which are intended to be used in combination with Omixon HLA TWIN CE certified IVD software for the identification and definition of Class I and II Human Leukocyte Antigens (HLA) and is for use in HLA typing utilizing the Illumina® MiSeq and MiniSeq Next Generation Sequencing platforms. The Holotype HLA provides human histocompatibility information of HLA Class I (A, B, and C) and Class II (DQB1 and DRB1) loci using human genomic DNA.
	Holotype HLA 96/5 Configuration B & CE v2 (REF: H24)	
	Holotype HLA 96/5 Configuration C & CE v2 (REF: H26)	

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 694131**
Date: **2022-05-23**
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Date	Reference Number	Action
18 December 2018	8943907	First Issue.
05 February 2019	8576664	Traceable to NB 0086.
30 January 2020	3099828	Change review - addition of new device configurations in the device table.
27 March 2020	3152705	Change – Addition of critical subcontractor.
08 December 2020	3328949	Change – Addition of critical subcontractor; removal of three devices from scope of certification.
23 May 2022	3643087	Change – New Legal Manufacturer address, addition of critical subcontractor Renewal.
Non-significant changes approved after the 26th May 2022 as per the Transitional Provisions of IVDR Article 110.3		
26 March 2024	30119263	Amended – change of subcontractor address

Inspiring trust for a more resilient world.

26 March 2024

Omixon Biocomputing Ltd.
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To whom it may concern,

The transitional provisions specified in IVDR Article 110(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26th May 2022.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under IVDR Article 110(3) and as per the guidance provided in MDCG 2022-6. The related IVDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 694131	98/79/EC Annex IV excluding Sections 4 and 6	30119263	Amended – change of subcontractor address

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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