By Royal Charter

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.**
Fehérvári út 50-52
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):

Albert Roossien, Regulatory Lead

First Issued: **2018-12-18** Date: **2019-02-05** Expiry Date: **2023-12-17**

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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.
Fehérvári út 50-52
Budapest
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NBOG code (s)	Device description	Intended purpose
Annex II List B		
IVD0306	**HLA NAT assays** Holotype HLA 96/11-Configuration A & CE v2 (REF H72) Holotype HLA 96/11-Configuration B & CE v2 (REF H76) Holotype HLA 24/11-Configuration A1 & CE v2 (REF H62) 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) Holotype HLA 96/7-Configuration A & CE v2 (REF H32.1)	HLA typing assays to detect HLA-DR, HLA-A and HLA-B tissue types by utilizing NGS technology

First Issued: **2018-12-18** Date: **2019-02-05** Expiry Date: **2023-12-17**

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NBOG code (s)	Device description	Intended purpose
Annex II List B		
	Holotype HLA 96/7-Configuration B & CE v2 (REF H34.1) Holotype HLA 24/7-Configuration A1 & CE v2 (REF H52.1) 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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Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 694131**
Date:	**2019-02-05**
Issued To:	**Omixon Biocomputing Ltd.** **Fehérvári út 50-52** **Budapest** **1117** **Hungary**

Subcontractor:	**Service(s) supplied**
Integrated DNA Technologies, Inc. 1710 Commercial Park Coralville Iowa 52241 USA	**Manufacture**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 694131**

Date: **2019-02-05**

Issued To: **Omixon Biocomputing Ltd.**
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Date	Reference Number	Action
18 December 2018	8943907	First Issue.
Current	8576664	Traceable to NB 0086.

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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.
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