

EC Certificate - Full Quality Assurance

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

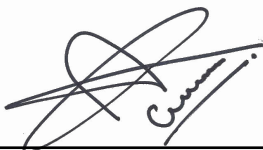
No. CE 694131
Issued To: **Omixon Biocomputing Ltd.**
Fehérvári út 50-52
Budapest
1117
Hungary

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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Page 1 of 3

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.

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Supplementary Information to CE 694131

Issued To:

Omixon Biocomputing Ltd.
Fehérvári út 50-52
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Hungary

NBOG code (s)	Device description	Intended purpose
Annex II List B		
IVD0306	<p>HLA NAT assays</p> <p>Holotype HLA 96/11-Configuration A & CE v2 (REF H72)</p> <p>Holotype HLA 96/11-Configuration B & CE v2 (REF H76)</p> <p>Holotype HLA 24/11-Configuration A1 & CE v2 (REF H62)</p> <p>Holotype HLA 24/11-Configuration A2 & CE v2 (REF H64)</p> <p>Holotype HLA 24/11-Configuration A3 & CE v2 (REF H66)</p> <p>Holotype HLA 24/11-Configuration A4 & CE v2 (REF (H68)</p> <p>Holotype HLA 96/7-Configuration A & CE v2 (REF H32.1)</p>	<p>HLA typing assays to detect HLA-DR, HLA-A and HLA-B tissue types by utilizing NGS technology</p>

First Issued: **2018-12-18**

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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.

EC Certificate - Full Quality Assurance

Supplementary Information to CE 694131

Issued To:

Omixon Biocomputing Ltd.
Fehérvári út 50-52
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1117
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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)	

First Issued: **2018-12-18**

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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.
 Fehérvári út 50-52
 Budapest
 1117
 Hungary

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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