

TITLE: **DECLARATION OF CONFORMITY OF THE HOLOTYPE HLA PRODUCTS**

DOCUMENT NO. **CE-HOLOTYPE HLA**

STATUS: **CURRENT**

DoC01

ISSUED: **5TH FEB, 2019**

VERSION: **9**

Company name: Omixon Biocomputing Ltd

Visiting address: Fehérvári út 50-52/6

City: Budapest

Post code: H-1117

Country: Hungary

Telephon /fax:

Omixon Biocomputing Ltd. (Fehérvári út 50-52/6, Budapest, Hungary 1117) under its own exclusive responsibility hereby declares that the distributed CE marked devices listed on the attached product list conform to Directive 98/79/EC of the European parliament of the council of 27 October 1998 on in vitro diagnostic medical device.

Holotype HLA products:

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
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

Device classification of Holotype HLA products: Annex II list B;

Conformity assessment route for Holotype HLA products:

- Annex IV: EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE SYSTEM)

In addition, we ensure and declare that the distributed CE marked medical devices meet the provisions of the EC-directive which applies to them.



This Declaration of conformity covers the Holotype HLA products as specified in the product list belonging to this declaration.

Notified Body Name: BSI Group The Netherlands B.V.


Address: John Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Identification Number: 2797

EC certificate number: CE 694131

Expiry Date: 17th Dec, 2023

Annex: Product list

Name	Peter Meintjes	 Signature
Function	Chief Executive Officer	
Place of issue	Budapest	
Date of issue	5 th Feb, 2019	



Annex to Declaration of conformity of the Holotype HLA: product list

Company name: Omixon Biocomputing Ltd

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This product list belongs to the Declaration of Conformity of the Holotype HLA, and specifies the CE marked products concerned that Omixon Biocomputing Ltd. intends to distribute in conformity with the provision of Council Directive 98/79/EC 27 October 1998, concerning in vitro diagnostics medical devices.

The following list identifies the products with product name and product number:

Product name	Number of reactions	Product reference number
Holotype HLA 96/11 Configuration A & CE v2	96	H72
Holotype HLA 96/11 Configuration B & CE v2	96	H76
Holotype HLA 24/11 Configuration A1 & CE v2	24	H62
Holotype HLA 24/11 Configuration A2 & CE v2	24	H64
Holotype HLA 24/11 Configuration A3 & CE v2	24	H66
Holotype HLA 24/11 Configuration A4 & CE v2	24	H68
Holotype HLA 96/7 Configuration A & CE v2	96	H32.1
Holotype HLA 96/7 Configuration B & CE v2	96	H34.1
Holotype HLA 24/7 Configuration A1 & CE v2	24	H52.1
Holotype HLA 24/7 Configuration A2 & CE v2	24	H56
Holotype HLA 24/7 Configuration A3 & CE v2	24	H58
Holotype HLA 24/7 Configuration A4 & CE v2	24	H60