

EC Type-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex V

No. **CE 643322**
Issued To: **Omixon Biocomputing Ltd**
Fehérvári út 50-52
Budapest
1117
Hungary

In respect of:

Holotype HLA

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex V, the type conforms to the relevant provision of 98/79/EC.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-03-24**

Date: **2018-04-09**

Expiry Date: **2021-03-23**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 643322

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Products:

Holotype HLA 24/7 - Configuration A1 & CE (REF H52)
Holotype HLA 96/7 - Configuration A & CE (REF H32)
Holotype HLA 96/7 - Configuration B & CE (REF H34)
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)

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Certificate History

| Date | Reference Number | Action |
|-----------------|------------------|---|
| 24 March 2016 | 10158746 | First Issue. |
| 30 August 2016 | 10164246 | Significant Change – extension of shelf life from 9 to 12 months, change of sequencing reagents and analysis parameters, increase in volume of library preparation reagents. |
| 26 October 2016 | 10166694 | Extension of product life to 17 months. |
| 27 April 2017 | 10166054 | Change – Deletion of Children’s Hospital of Philadelphia as subcontractor for final inspection, addition of Stefan-Morsch-Stiftung as subcontractor for final inspection. |
| 30 October 2017 | 8802039 | Extension to scope – addition of different product configuration: Holotype HLA 96/7 – Configuration B & CE. |
| Current | 8899111 | Extension to scope – addition of different product configurations for Holotype HLA 24/7 and HLA 96/7 assays (H52.1, H56, H58, H60, H32.1, H34.1) and addition of new products Holotype HLA 24/11 and HLA 96/11 configuration assays (H72, H76, H62, H64, H66, H68). |

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