

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Omixon Biocomputing Ltd
Fehérvári út 50-52
Budapest
1117
Hungary

Holds Certificate Number:

MD 643327

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, distribution, servicing and customer support for in-vitro diagnostic software and diagnostic nucleic acid kits for HLA tissue typing and MICA, MICB genotyping utilizing next generation sequencing technology.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-03-17

Latest Revision Date: 2019-02-19

Effective Date: 2019-03-01

Expiry Date: 2022-02-28

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Certificate No: **MD 643327**

Location

Omixon Biocomputing Ltd.
Fehérvári út 50-52
Budapest
1117
Hungary

Omixon Biocomputing Ltd.
Papírgyar u. 58-59
Budapest
1038
Hungary

Registered Activities

The design, development, manufacture, distribution, servicing and customer support for in-vitro diagnostic software and diagnostic nucleic acid kits for HLA tissue typing and MICA, MICB genotyping utilizing next generation sequencing technology.

The design, development and final inspection of diagnostic nucleic acid kits for HLA tissue typing and MICA, MICB genotyping utilizing next generation sequencing technology.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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