

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Omixon Biocomputing Ltd.
Kaposvár u. 14-18
Budapest
1117
Hungary

Facility ID Number: F005931

Holds Certificate No:

MDSAP 765123

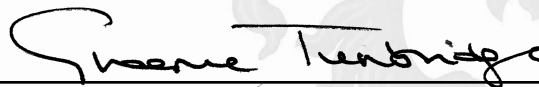
The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Design, development, manufacture, distribution and service of in vitro diagnostic medical devices (reagents and software) based on molecular genetic testing for tissue typing, disease status, therapeutic status and transplantation diagnostics.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-04-03

Effective Date: 2025-03-01

Expiry Date: 2028-02-28



BSI Group America Inc. is an MDSAP recognised auditing organization

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