By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 747706 R000

Manufacturer: Omixon Biocomputing Ltd.

Address:
Kaposvár utca 14-18
Budapest
H-1117
Hungary

Single Registration Number: HU-MF-000003018

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-05-28**

Current Issue Date: **2024-10-08**

Starting Validity Date: **2024-10-08**

Expiry Date: **2029-05-27**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W010304 – Tissue typing reagents IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	The identification and definition of Class I (A, B, and C) and Class II (DQA1, DQB1, DRB1, DRB3/4/5, DPA1, DPB1) genes of the Human Leukocyte Antigens (HLA) complex from human genomic DNA derived from human whole blood.
W020501 – Nucleic Acid Testing Instruments Except Micro-Arrays IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	Medical device software intended for the analysis of sequencing data of Class I (A, B, and C) and class II (DQA1, DQB1, DRB1, DRB3/4/5, DPA1, DPB1) genes of the Human Leukocyte Antigens (HLA) complex.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-05-28	3817988	Issued
Current	30269970	Supplemented – Addition of new device group

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