



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** ...making excellence a habit."

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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Device Schedule: Class D, C and B devices

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