

EU Quality Management System Certificate

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

IVDR 798482 R000

Manufacturer: Aiforia Technologies Plc

Address:

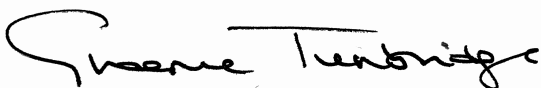
Pursimiehenkatu 29-31 D
Helsinki
00150
Finland

Single Registration Number: FI-MF-000008986

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: **2025-02-18**

Current Issue Date: **2025-02-18**

Starting Validity Date: **2025-02-18**

Expiry Date: **2030-02-17**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0202 – Hematology / Histology / Cytology Instruments IVP 3010 – In vitro diagnostic devices which require knowledge regarding microscopy	In vitro diagnostic software devices intended for use with digitised histology slides to aid in the diagnosis of cancer.



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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
Current	30025786	Issued



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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.

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