

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

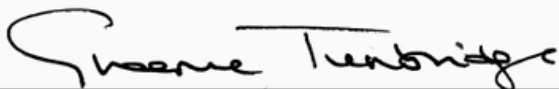
Finland

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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