

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 792790 R000

Manufacturer: AI LABS GROUP, S.L.

Address:

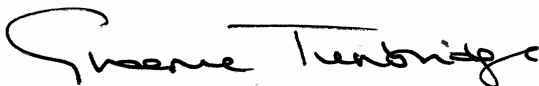
C/ Gran Via 1
BAT Tower
Bilbao
Bizkaia
48001
Spain

Single Registration Number: ES-MF-000025345

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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: **2026-09-15**

Current Issue Date: **2026-09-15**

Starting Validity Date: **2026-09-15**

Expiry Date: **2031-09-14**

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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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Device Schedule: Class III and Class IIb devices

Class IIb

General medicine diagnosis and monitoring instruments - Medical device software

Intended purpose

The device is a computational software-only medical device leveraging computer vision algorithms to process images of the epidermis, the dermis and its appendages, among other skin structures, enhancing efficiency and accuracy of care delivery, by providing:

- an interpretative distribution representation of possible International Classification of Diseases (ICD) categories that might be represented in the pixels content of the image
- quantifiable data on the intensity, count and extent of clinical signs such as erythema, desquamation, and induration, among others

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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 Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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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	30001390	Issued



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