DERMARASH - REGULATORY POSITION STATEMENT

April 22, 2026

Product Name: DermaRash (iOS application)

Developer: Evren Haznedaroglu

Version reviewed: 1.5

Submission ID: d0c561c9-51c3-4840-a11f-8a36e0d5e95c

1. INTENDED USE

DermaRash is a consumer, AI-assisted EDUCATIONAL application that allows a user to learn about general skin-appearance information that visually resembles a photo they have captured of themselves. All output is informational and backed by citations to authoritative public health and dermatology sources (American Academy of Dermatology, National Health Service UK, Mayo Clinic, DermNet NZ, NIH MedlinePlus, World Health Organization).

2. NOT A MEDICAL DEVICE - BASIS OF SELF-CLASSIFICATION

DermaRash does not diagnose, cure, mitigate, prevent, or treat any disease. It does not recommend, prescribe, or adjust medication, dosage, or any form of clinical treatment. It does not perform clinical measurement or provide care-routing decisions.

2.1 United States - FDA 21 CFR 880 / General Wellness Guidance

(FDA, "General Wellness: Policy for Low-Risk Devices", Sept 2019)

DermaRash meets the criteria for a General Wellness product:

(a) its intended use relates to maintaining or encouraging a general state of health or a healthy activity (general awareness of skin appearance and public-source education);

(b) it does not present inherent risk to a user’s safety when used as intended, because it provides educational information only, carries a mandatory educational notice in the product, and is limited to visual reference notes and public-source reading links;

(c) no claim is made that it diagnoses, cures, mitigates, prevents, or treats any specific disease or condition.

2.2 European Union - MDR 2017/745, Annex VIII, Rule 11

DermaRash is not software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes. It provides general educational information only. It does not qualify as a medical device under Article 2(1) and is therefore outside the scope of MDR 2017/745.

2.3 United Kingdom - MHRA "Software and AI as a Medical Device"

DermaRash does not meet the functional definition of a Software as a Medical Device (SaMD) under the MHRA guidance because its output is purely educational and does not drive, inform, or support clinical decisions.

3. RISK CONTROLS EMBEDDED IN THE PRODUCT

(a) Mandatory consent screen before any data submission, disclosing what data is sent, to whom, and how it is used.

(b) Non-diagnostic terminology throughout the application (e.g. "Visible Features Summary", "Visible Feature Notes", "Public Reading Links").

(c) Educational banner and app notice on every report.

(d) Hard AI guardrails in all three supported languages forbidding diagnosis, prescription, dosage, and definitive clinical language.

(e) Curated public-source links shown with each report.

(f) No diagnosis, treatment, prescription, or care-routing language in the user-facing output.

4. DATA HANDLING

DermaRash does not use any third-party AI service. AI inference runs on self-hosted infrastructure operated by the developer at derma.idakim.net. User data is not used to train AI models, is not sold, and is not shared with advertisers. Full disclosure is available

at https://evrenhaznedaroglu2024-ops.github.io/derman/#privacy §5.

5. DECLARATION

I confirm that, based on the criteria above, DermaRash does not require regulatory clearance from the FDA, the EU MDR notified body system, or the UK MHRA, and is marketed strictly as a general-wellness, educational consumer application.

Signed: Evren Haznedaroglu

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Contact: info@idakimi.com • +44 744 192 2077