

## Derm AI

Public Declaration – Health Institution Exemption  
UK Medical Devices Regulations 2002

Last reviewed: June 2026  
Next review: June 2027

### 1. Purpose of this Declaration

This declaration is made under the Health Institution Exemption (HIE), which requires health institutions that manufacture medical devices, to draw up a public declaration for their HIE devices.

This declaration is made by Omnes Healthcare Ltd., as the health institution deploying Derm AI within its clinical services. Omnes Healthcare Ltd. is a wholly-owned subsidiary of Evergreen Health Solutions Ltd., and has sub-contracted the manufacture of Derm AI to Evergreen Health Solutions Ltd. as its parent company, in accordance with the sub-contracting provisions of the Health Institution Exemption. Evergreen Health Solutions Ltd. carries out that sub-contracted manufacture under the governance and control of Omnes Healthcare Ltd.

### 2. Identity of the Deploying and Manufacturing Entities

<b>Group</b>	Evergreen Health Solutions group (Evergreen Health Solutions Ltd. and its wholly owned subsidiary Omnes Healthcare Ltd.)
<b>Health institution (deploying entity)</b>	Omnes Healthcare Ltd.
<b>Registered Address</b>	Evergreen House, Clowes Street, Salford, M3 5NA
<b>Sub-contracted manufacturer (parent company)</b>	Evergreen Health Solutions Ltd.
<b>Registered Address</b>	Evergreen House, Clowes Street, Salford, M3 5NA

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### 3. Device Identification

<b>Device Name</b>	Derm AI
<b>Device Description</b>	Derm AI uses artificial intelligence (AI) to help clinicians prioritise patients with skin lesions. It analyses smartphone photos and patient information to assign a risk priority. It does not diagnose skin cancer or replace clinical judgement.
<b>Version</b>	YOLO model version 8.1.10 and classifier version 1.0.0

<b>Date of First Deployment</b>	1 <sup>st</sup> July 2026
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#### **4. Intended Purpose**

Derm AI is a standalone software medical device (SaMD) that incorporates artificial intelligence to function as a clinical decision support tool for case prioritisation of patients presenting with skin lesions. The software analyses patient-submitted macroscopic smartphone images of skin lesions together with patient-provided free-text descriptions and demographic information (age and sex) to generate a configurable risk priority classification.

The software does not provide a diagnosis, is not intended to rule in or rule out disease, and does not recommend patient management. Responsibility for clinical assessment, diagnosis, and patient management remains with the authorised user and, where appropriate, the supervising clinician.

The software is intended for use within healthcare organisations implementing local clinical pathways for the assessment of skin lesions. The specific deployment configuration, including the clinical workflow in which outputs are used, output threshold settings, and the level of clinical oversight applied, is determined by the deploying healthcare organisation under its clinical governance arrangements and documented in deployment-specific documentation.

#### **5. Declaration of Compliance with General Safety and Performance Requirements**

Omnes Healthcare Ltd., as the health institution deploying Derm AI, declares that Derm AI has been designed and developed by Evergreen Health Solutions Ltd. in accordance with the essential requirements set out in UK MDR 2002.