



# Skin Analytics Approved Hardware List

SA-001132-PR

# Document Control

## Document Information

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<b>Issue</b>	<b>Description of Change</b>
1	First version
2	Added list of approved hardware for DERM DS - the US variant of DERM in Section 5. Added DL200HR / iPhone 11 to approved OUS list. See CM-289.
3	Added DL1 Basic / iPhone SE to approved OUS list. See CM-309.
4	Updated to specify 'iPhone SE (2020)'. See CM-310.
5	Updated to add Default hardware and deleted reference to legacy version v2.2 in section 4. See CM-315.

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# 1. Introduction

This document sets out the list of approved hardware that can be used with the versions of DERM / DERM DS that have been released to the market, as well as which set of hardware is considered the Default device(s) in line with SA-004202-WI.

# 2. Reference Documents

Document Number	Title
SA-001133-DS	Device Qualification Method
SA-004202-WI	Sending Hardware for use with DERM (OUS) Work Instruction

# 3. Qualification Methods

Qualification of hardware suitable for use with DERM will be performed either as part of a clinical study or through a standalone device qualification study performed in accordance with the Device Qualification Method (SA-001133-DS).

The qualification process and list of approved hardware applies to both the UKCA class I and class IIa variants of DERM, and the US variant of DERM, called DERM DS.

A reference to the qualification evidence for each piece of hardware / software combination is provided in the below table.

# 4. Approved Hardware - OUS

Capture Device	Dermoscope	DERM v3	DERM v4
iPhone 6s	Dermlite DL1 Basic	Y	Y
Qualification evidence:		SA-001080-CS	SA-001080-CS
Samsung s6	Dermlite DL1 Basic	Y	Y
Qualification evidence:		SA-001080-CS	SA-001080-CS
iPhone 11	Dermlite DL1 Basic	Y - Default	Y - Default
Qualification evidence:		SA-001134-DS	SA-001134-DS

<b>iPhone 11</b>	<b>Dermlite DL200HR</b>	Y	Y
Qualification evidence:		SA-003692-DS	SA-003692-DS
<b>iPhone SE (2020)</b>	<b>Dermlite DL1 Basic</b>	--	Y
		--	SA-004127-DS

## 5. Approved Hardware - US (DERM DS)

<b>Capture Device</b>	<b>Dermoscope</b>	<b>DERM v3.1</b>
<b>iPhone 11</b>	<b>Dermlite DL200HR</b>	Y
Qualification evidence:		DERM-006 DERM-007 Clinical Studies

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