

# Competitor Compliance Assessment Checklist

F&G Strategy Academy · Module 5: The Competitor Audit

## 1. Product details

Product name \_\_\_\_\_  
Manufacturer name \_\_\_\_\_  
App Store / website URL \_\_\_\_\_  
Date of assessment \_\_\_\_\_  
Assessor name \_\_\_\_\_

## 2. MHRA DORS registration

Registered (yes / no) \_\_\_\_\_  
Date checked \_\_\_\_\_  
Screenshot reference \_\_\_\_\_

## 3. UKCA or CE marking

Mark displayed (yes / no) \_\_\_\_\_  
Approved Body identification number present (yes / no — required for Class IIa+)  
\_\_\_\_\_  
Screenshot reference \_\_\_\_\_

## 3a. Intended purpose statement

Discrepancies between the App Store intended purpose and the website marketing are a primary indicator of inferred medical purpose under MHRA DMHT guidance. Capture both on the same date to ensure comparability.

App Store intended purpose \_\_\_\_\_  
Website intended purpose \_\_\_\_\_  
Discrepancies noted (yes / no) — notes:  
\_\_\_\_\_  
Screenshot reference \_\_\_\_\_

## 4. Clinical claims documented

List each claim with URL, date and screenshot reference.

Claim	URL	Date	Screenshot ref

## 5. NHS deployment evidence

Deployed in NHS (yes / no) \_\_\_\_\_  
Evidence source (NHS Apps Library / NHS Supply Chain / NICE / other)  
\_\_\_\_\_  
Screenshot reference \_\_\_\_\_

## 6. Overall compliance assessment

- Clearly compliant
- Borderline (reasonable experts could disagree)
- Clearly non-compliant (registration absent plus clinical claims)
- Insufficient information to assess

## 7. Escalation decision

- Report to MHRA
- Monitor and reassess in 30 days
- No action

Reasoning \_\_\_\_\_

Date of decision \_\_\_\_\_