GLOBAL UDI
CONSULTANTS

REGULATORY UPDATE · APPLE APP STORE · SPRING 2026

New Apple requirements for medical device apps (2026)

From spring 2026, Apple is implementing stricter oversight for health applications that function as medical devices across the US, UK, and EEA. Apps that perform diagnosis, treatment, or medical monitoring face a higher level of scrutiny.



Spring 2026 Stricter oversight begins	**US · UK · EEA** Regions covered	**FDA · CE · UKCA** Evidence Apple now asks for

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WHAT IS CHANGING?

Apple becomes an additional regulatory checkpoint.

Apple is transitioning from a distribution platform to an additional regulatory checkpoint. Developers are now required to:

REQUIREMENT 01

Formally declare status

Declare within App Store Connect whether an app qualifies as a regulated medical device and specify the regions where it is available.

REQUIREMENT 02

Provide regulatory evidence

Submit supporting documentation such as FDA clearance, CE marking, or equivalent approvals.

REQUIREMENT 03

Increase transparency

Provide clear information regarding intended use, safety instructions, limitations, and full manufacturer contact details.

REQUIREMENT 04

Meet stringent review standards

Apps will be assessed more closely for clinical validity, data accuracy, and user safety.

WHY IT MATTERS · HOW WE HELP

Your App Store data must match your official registrations.

As your regulatory partner, Global UDI and its specialist partner network help you meet these new platform requirements, including EU Authorized Representative and UK Responsible Person support.

Because Apple now requires formal regulatory evidence and manufacturer transparency, well-managed technical documentation and CE/UKCA marking are essential for App Store approval.

We make sure the data you submit to Apple matches the official registrations held in the US, EU and UK, preventing delays or removals from the store.

1. Technical documentation and CE/UKCA marking managed
2. Regulatory evidence and manufacturer details ready for Apple
3. Data submitted to Apple matches FDA, EU and UK registrations
4. No delays or removals from the store

FOR DEVELOPERS

Developing or distributing a medical device app? **Align your regulatory approvals with Apple's new requirements.**

REGULATORY & QUALITY SERVICES

Support across the full medical device lifecycle.

Regulatory, quality and technical support, from submissions and QMS to technical files, risk management and audits, delivered by Global UDI with our specialist partner network.

01

Regulatory

- Regulatory affairs: preparing CE Mark, FDA and international regulatory submissions
- Medical device vigilance and reporting systems
- Regulatory inspection gap analysis
- Site / company representative for regulatory inspections
- Clinical trial / performance evaluation advice, incl. clinical strategy, protocol design, IRB / IEC and Competent Authority submissions, and clinical study report writing

02

Quality System / QMS

- QMS design, implementation and maintenance to ISO 9001, ISO 13485 and QMSR (Part 820)
- GMP and FDA compliance
- Validation of equipment, processes, test methods, facilities, product software
- Business and computer systems validation, incl. Part 11 and electronic records & signatures
- Process mapping, management review, QMS gap analysis and remediation, design control

03

Technical File / Design Dossier

- Technical and design file reviews
- Product classification
- Clinical evaluation reports
- Biological safety evaluations

04

Risk Management

- Risk management (ISO 14971)
- A risk-based approach to meeting your quality and regulatory needs

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OUR SERVICES (CONTINUED)

05

Audits

- Internal and external auditing
- Supplier approval and audit program implementation and management
- Pre-audit preparations (FDA, MHRA, Notified Body, unannounced)
- Post-audit advice and guidance
- Mock Notified Body / FDA audits

06

Support activities

- General QA support / advice on ISO 9001, 13485, FDA and EU GxP
- Documentation, change control, validation, CAPA / incident management
- Investor diligence: quality and regulatory due diligence

07

Other

- Outsourcing organisation
- Training: GMP training with an FDA / MHRA focus

WHY WORK WITH US

A flexible approach, tailored to you.

Your workload changes from project to project, and so should your support.

Bring us in for one submission, one market or the whole portfolio. You get exactly the help you need, when you need it.

- Expertise in medical devices and IVDs
- Proficiency in biological, blood establishment & stem cell industries
- Straightforward and successful regulatory routes to market
- CE, FDA, PMA, Pre-IDE, IDE, NICE, MHRA experience
- International regulatory submissions
- A hands-on approach to achieving approvals
- QMS implementation / maintenance

ALSO FROM GLOBAL UDI

UDI data collection & submission to **FDA GUDID, EU EUDAMED and TGA AusUDID**, UDI label design and printing, and IQ/OQ/PQ validation.

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NEXT STEP · FREE CONSULTATION

Book a free 15–30 minute video consultation call.

Our team will identify the gaps.

IN THE CALL WE'LL REVIEW

- Whether your app qualifies as a regulated medical device
- Which regions and approvals Apple will ask about
- Your FDA, CE / UKCA evidence and manufacturer details
- Gaps between your App Store data and official registrations

YOU'LL LEAVE WITH

- A list of the gaps we found
- What Apple will expect from your listing
- Recommended next steps
- No obligation

Book your free call

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Email us →

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Guides, templates, videos and the EUDAMED / GUDID readiness check.

Global UDI is a registered third-party GUDID & EUDAMED data collector and submitter.