

Declaration of Conformity

Document reference: DoC-CADENCE-001 v0.5 · Date: 2026-03-20

Manufacturer

Cadence Health Ltd

Company No. 17043196

3rd Floor, 86-90 Paul Street, London, EC2A 4NE, United Kingdom

Person Responsible for Regulatory Compliance

Bradley Phelps, CEO / Clinical Safety Officer

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Device Identification

Device name: Cadence

Software version: 1.4.0

GMDN code: 64275 — Patient general health self-management software

Classification: Class I (non-measuring, non-sterile)

Applicable regulation: UK Medical Devices Regulations 2002 (SI 2002/618, as amended), Part II, Annex IX

MHRA Registration

DORS registration reference: 2026031601473996

Account number: 0000037736

Registration date: 2026-03-16

Intended Purpose

Cadence is a software application that provides educational and behavioural support content for adult patients (18+) prescribed GLP-1 receptor agonist medications (tirzepatide or semaglutide) for weight management. The software delivers pharmacokinetically-grounded daily content, symptom tracking, and self-management support across a 52-week treatment programme.

Cadence does **NOT**: provide medical diagnoses, recommend or suggest dose changes, perform automated clinical risk assessment, or replace clinical judgement. All content is informational and supportive in nature.

Essential Requirements

This device conforms with the applicable Essential Requirements of Annex I to the UK Medical Devices Regulations 2002 (Part II), as documented in the Technical File (§03 Essential Requirements Checklist).

Applied Standards

Standard	Title
ISO 14971:2019	Application of risk management to medical devices
IEC 62304:2006+A1:2015	Medical device software — Software life cycle processes
IEC 62366-1:2015+A1:2020	Medical devices — Usability engineering

DCB0129	Clinical Risk Management: its Application in the Manufacture of Health IT Systems
DCB0160	Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

Safety Classification

IEC 62304 software safety class: B

Clinical risk: Residual risk acceptable (Technical File §04)

Benefit-risk: Favourable (Technical File §07)

Declaration

I, Bradley Phelps, as the Person Responsible for Regulatory Compliance for Cadence Health Ltd, hereby declare that the device described above conforms with the applicable provisions of the UK Medical Devices Regulations 2002 (SI 2002/618, as amended).

This declaration is issued under the sole responsibility of the manufacturer.

Signed:

Bradley Phelps

Position:

CEO / Clinical Safety Officer, Cadence Health Ltd

Date:

2026-03-20