

Matresa

Intended Use Statement, Use Statement and Safety Information

MHRA DORS — Class I Medical Device

Part 1: Intended Use Statement (MHRA DORS — Class I)

Product

Name: Matresa

Version: 1.4

Intended Use

Matresa is a Software as a Service (SaaS) platform combining a mobile application (iOS and Android) and a supporting secure web administration system, designed to provide preventative, educational and wellbeing support to women from pregnancy through the first two years of motherhood.

The mobile application enables users to complete structured wellbeing check-ins, record and review personal notes relating to their own maternity and clinical appointments, access a moderated peer support community, and complete a structured 6–8 week postnatal check comprising validated screening instruments (PHQ-9, EPDS, GAD-7). Responses to these instruments are recorded and, where the user chooses, compiled as item-by-item answers into a document that may be shared with her GP or midwife. No score, severity band, or clinical interpretation is calculated, displayed, or otherwise generated by the software from these responses under the current version of the application.

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The web administration system supports Matresa staff in user and licence management, content management, and moderation of the peer support community. It is not accessed by end users and does not process or generate any clinical output.

The platform integrates optional wearable data (via Apple HealthKit and Android Health Connect) to support general wellbeing tracking, and includes an AI-based assistant (“Florrie”) that directs users to approved Matresa educational content in response to their questions; Florrie’s responses are restricted to approved content only and do not include medical advice, diagnosis, or personal medical opinions. An optional recording and transcription feature (“Second Ear”) allows users to record their own medical appointments for personal reference and may extract non-clinical follow-up actions (e.g. “book a follow-up appointment”) for the user’s own to-do list.

The device is a wellbeing, self-monitoring and information tool, not a diagnostic tool, and is intended to be used in conjunction with, not in place of, advice from a GP, midwife, obstetrician or other qualified healthcare professional.

Intended Medical Indication

None. Matresa is not intended for the diagnosis, screening, treatment, monitoring, cure or prevention of any disease or medical condition.

Contraindications

Not intended for use in a medical emergency. Not intended to replace consultation with, or the clinical judgement of, a GP, midwife, obstetrician or other qualified healthcare professional.

Patient Population

Matresa is designed to support pregnant women and mothers within the first two years postpartum, aged 18 and over. These users typically experience a sequence of wellbeing, informational and emotional needs across pregnancy, birth, the postnatal period, and return to work, and may be seeking general health information, self-monitoring tools, and peer support alongside their existing clinical care from a GP, midwife or obstetrician.

Matresa is intended to be used by individual (B2C) users and by employees of organisations providing Matresa as a workplace benefit (B2B), including a dedicated Work Screen supporting the return-to-work transition. It

empowers users to record and reflect on their own wellbeing, appointments and journey milestones, while continuing to rely on their healthcare providers for any clinical assessment, diagnosis or treatment decisions.

User Profile

Meet Priya, a 32-year-old woman who is 24 weeks pregnant with her first child. Priya uses Matresa daily to log her mood, symptoms and general wellbeing through the Daily Update feature, and to keep a diary of her pregnancy journey alongside notes from her midwife appointments. She has connected her Apple Watch so her sleep and activity data feed automatically into the app.

Priya has questions between appointments and uses the “Ask Florrie” feature to find relevant, Matresa-approved educational content rather than searching the open internet. She also participates in the moderated Community Forum, where she can ask questions and share experiences with other users at a similar stage of pregnancy, in a space that protects her privacy through a forum nickname rather than her real name.

As she approaches 6–8 weeks postnatal, Priya will be prompted to complete a structured postnatal wellbeing check. Her responses are recorded for her own reference and, if she chooses, compiled into a document she can share with her GP or midwife to discuss at her review appointment — Matresa does not interpret or score her responses on her behalf. Throughout, Matresa acts as a companion to Priya's existing maternity care, not a replacement for it, and consistently signposts her to speak to her GP, midwife or emergency services where appropriate.

Use Environment Including Software/Hardware

Matresa is used primarily in the home, or any non-clinical setting, via a personal iOS or Android smartphone, without supervision by a healthcare professional at the point of use. Users interact with the mobile application independently, at times of their own choosing, integrating it into daily life across pregnancy and the postnatal period.

The platform also supports a blended use case for B2B/corporate users, where an employer provides access to Matresa as a workplace wellbeing benefit; in this context, users may additionally access work-related content and a return-to-work programme via the Work Screen, without altering the fundamentally non-clinical, self-directed nature of app use.

Matresa staff (not end users) additionally operate a secure web-based administration system for user/licence management, content management, and moderation of the peer support community; this administration system is used in an operational/administrative office setting and does not itself constitute a use environment for clinical purposes, as it does not process, generate, or present any clinical output to any user.

The mobile application optionally integrates with the user's own wearable device (e.g. Apple Watch, Garmin, Oura) via the phone's native health platform (Apple HealthKit or Android Health Connect), where the user has granted permission, to enhance general wellbeing tracking (sleep, heart rate, steps, HRV).

Operating Principle

Matresa is a Software as a Service (SaaS) platform, combining a Flutter-based mobile application (iOS and Android) with a .NET Core/Angular-based secure web administration system. It is not a standalone hardware device, but relies on the user's own smartphone hardware and secure internet connectivity to function.

The mobile application enables users to complete onboarding and ongoing structured check-ins, record diary entries and personal notes, access educational content targeted to their pregnancy/postnatal stage, and participate in a moderated community forum. Where enabled by the user, wearable data is integrated via Apple HealthKit or Android Health Connect.

An AI-based retrieval-augmented assistant (“Florrie”) responds to user questions by retrieving and directing users to approved Matresa content only, using vector search over indexed content; it does not access the external internet and does not generate original clinical guidance. Community forum posts are screened by an AI/rule-based moderation system before publication, with posts flagged as potentially unsafe or inappropriate held for human review by Matresa staff before publication.

An optional recording feature (“Second Ear”) allows users to record their own medical appointments; recordings are transcribed via a UK-hosted transcription service, and the transcript may be processed to extract non-clinical, practical follow-up actions (e.g. medication reminders, booking a follow-up appointment) for the user's personal to-do list. This process does not generate or present any clinical interpretation of appointment content.

Security measures include mandatory two-factor authentication for all web administration accounts, role-based and API-enforced permission controls, session token hashing, and IP logging to support security audits.

Variants / Accessories

- iOS or Android smartphone (Flutter-based mobile application)
- Optional: compatible wearable device integrated via Apple HealthKit or Android Health Connect (e.g. Apple Watch, Garmin, Oura Ring). Note: any Oura Ring integration is indirect, via Apple Health/Health Connect; there is no direct Oura API integration in this phase.

Part 2: Use Statement

Matresa is a digital maternal health platform providing preventative, educational and wellbeing support to women from pregnancy through the first two years of motherhood.

The app enables users to complete structured wellbeing check-ins, including questions drawn from validated frameworks such as PHQ-9, the responses to which are recorded within the user's account. No score, pattern, or interpretation is calculated or displayed based on these responses under the current version of the app. Users can record and review notes from their own maternity and clinical appointments, access a moderated peer support community, and complete a 6 to 8 week postnatal wellbeing check, the responses to which may be compiled, without algorithmic scoring or interpretation, into a summary for the user's own reference and voluntary discussion with her GP or midwife.

Matresa is intended for pregnant women and mothers within the first two years postpartum, aged 18 and over, as a source of general health information, self-monitoring and peer support. It does not diagnose, treat, cure or prevent any disease or medical condition, and it does not provide automated clinical decision-making. The app displays static, general educational content — the same for all users regardless of their individual responses — signposting users to seek advice from their GP, midwife, obstetrician or, in an emergency, urgent medical care. Matresa is intended to support, not replace, the relationship between a user and her healthcare provider.

Part 3: Safety Information

Matresa is a preventative wellbeing tool. It does not replace professional medical advice, diagnosis or treatment. Users should always seek the advice of their GP, midwife, obstetrician or other qualified healthcare professional with any questions about pregnancy, postnatal recovery or their own or their baby's health, and should never delay seeking professional advice because of information provided through the app.

Matresa does not provide emergency medical services. In a medical emergency, users should call 999 or attend their nearest emergency department immediately.

The app's wellbeing check-ins and screening questionnaires are informational tools and are not a substitute for clinical assessment. Completing a check-in does not rule out a medical condition, and the app's general signposting content is not a diagnosis or clinical assessment.

Content relating to pregnancy or baby loss is only made available following specialist clinical review and is not served automatically.

The moderated community feature is for peer support. It is not a clinical service and should not be used to seek urgent medical advice.

Any health data entered into the app, including blood pressure, is self-reported by the user. The app does not connect to or interpret data from medical monitoring devices.

No contraindications are known. Matresa is not intended for use in a medical emergency or as a substitute for antenatal, intrapartum or postnatal clinical care.