Intended Use Statement

[GENERATED DRAFT]

Template Guidance

This template is a generated draft. Each document section represents a specific topic that you should consider and/or modify to match your company's practice.

- We suggest you keep language at a high enough level such that it stays representative for at least a year.
- Helpful tips or information is highlighted in <mark>orange</mark> and designed to be deleted.
- Example answers are highlighted in <mark>red</mark> and are designed to be deleted.
- Text highlighted in <mark>yellow</mark> or <mark>blue</mark> is system generated and should be given special attention. References to other documents and/or sections are in **bold**.

Ensure all relevant stakeholders have reviewed the document, and that approvals are recorded under **Document Management**.

Once ready, you can remove this cover page and any unwanted branding before marking the document as approved in Assuric. This will save a versioned copy.

Intended Use Statement - ==Appointment Manager==

The Intended Use Statement is a short document that clearly outlines the intended purpose and use of the product, and the context in which it is intended to be used. It is an absolutely essential requirement for software as a medical device (SaMD) products, and also a very useful exercise for non-medical device digital health products.

==[GENERATED DRAFT]==

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Document Management

Version	Date	Description	Approval(s) (Name, Job Title)
==v1.0==	==February 5, 2025==	==First version==	==Name, Job title==

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Product overview

Give a few sentences of overview and background to the product.

Application that allows patients to view, schedule and change their appointments online or on their smartphone.
Patients are given reminders to attend their appointments, and are able to cancel appointments easily if they cannot attend, leading to fewer wasted appointments.
Clinicians can interact with patients if there are any changes to the appointment, for example if they are sick or if the location changes.

Intended scope of use

What phase of the product life cycle is the product in? Is this statement referring to a pilot phase or a full deployment? In how many hospitals, wards, GP practices, clinics, operating theatres etc will the product be used in (approximately)?

Intended indication or function

What is the specific purpose or function of the product? What are its aims?

The product is not classified as Software as a Medical Device (SaMD), and does not perform any medical functions, like diagnosis, treatment, or prediction or prevention of clinical outcomes.

Intended patient population

What specific patient group will your product benefit?

For example:
Adults aged ≥18 who are registered with the GP practice deploying our product
Exclusion criteria: paediatric population, aged <18

Intended user groups

Who are the key user groups of your product? If more than one group, who are the primary users, secondary and/or tertiary users?

For example

Primary users are adult patients with X medical condition who are registered with the GP practice
Secondary users are healthcare practitioners within the GP practice, specifically doctors and specialist nurses
Tertiary users are our company staff for administrative purposes

Intended part of the body

This is likely not relevant but if your product has a physical component, does it come into contact with any part of the body?

Not applicable

Use environment

Where exactly is the software intended to be used? Is it a mobile phone application, a web application or a desktop application? Does it require installation? Is it cloud-based or hosted locally? Is it to be used on hardware supplied by the deploying healthcare organisation or the manufacturer? Where is it to be used e.g. a hospital ward, an operating theatre, an outpatient clinic etc?

For example:
- The product is a mobile phone application, downloaded and used by patients (primary users) on their personal mobile phone devices.
- There is also a cloud-based web application that is used by healthcare practitioners (doctors and specialist nurses) in their browser on the GP practice computers.

Operating principle

Map out a step-by-step process that gives a simple overview of the user journey, including information flow, when the software is in use. If you are using AI components, it is useful to provide a simple diagram of your algorithm architecture or pipeline.
How does the product fit within existing workflows or care pathways? Does the product replace any existing workflows or pathways?

Can you think of any foreseeable misuse of the product? Could the software be used in a way that you, as the manufacturer, don't intend? For example, could the software by used by someone who is not the intended user