Intended Use

Mapping of Requirements to Document Sections

MDR Class	MDR Section	Document Section
(All)	Annex II, 1.1 a) - d), h), i)	(All)

ISO 14971:2019 Section	Document Section
5.2	(All)

IEC 62366-1:2015 Section	Document Section
5.1	(All)

Product

- Name: *<product name>*
- Version: *<product version>*
- Basic UDI-DI: *<insert UDI-DI, if/when available>*

Intended Use

Describe the core medical functionality of your device and how it treats, diagnoses or alleviates a disease. Keep it high-level so that this description is true for as long as possible even when the device is updated.

Intended Medical Indication

Describe the condition(s) and/or disease(s) to be screened, monitored, treated, diagnosed, or prevented by your software. Importantly, also list exclusion criteria: Maybe patients with a certain diagnosis should not be using your device.

Contraindications

List anything that you want to explicitly exclude from your intended use.

Patient Population

Describe the patient population your software is intended to be used on. Note that this may overlap with the user profile (section below), but not necessarily. Your software could be used by physicians to diagnose diseases in patients, so in that case, they don't overlap. Some ideas for characteristics to describe: Age group, weight range, health, condition(s).

User Profile

Describe the typical user of the software. Some ideas could be: Qualifications, prior training (for your software), technical proficiency, time spent using the software.

Use Environment Including Software/Hardware

Describe the typical use environment. What sort of devices is this running on? Does the software only run on one device or multiple devices? Is it loud and chaotic like in an emergency ward? How's the lighting?

Also, add other software or hardware which is required by your device. Most commonly, apps require users to have a smartphone with a compatible operating system (iOS / Android).

Operating Principle

It's kind of a stretch to describe the "operating principle" of software. I guess this makes more sense for hardware devices. In any case, I'd just generally state what sort of input goes in and what output comes out, e.g. you could be processing images and returning diagnoses.

The device is stand-alone software. It receives input from the user and outputs information.

Part of the Body / Type of Tissue Interacted With

The device is stand-alone software. It receives input from the user and outputs information. It doesn't come in contact with tissue or bodily fluids.

Variants / Accessories

Describe variants and/or accessories of/to this device, if applicable. For typical stand-alone software of startups, this shouldn't be applicable.
