Essential Requirements MDD (93/42/EEC)

This document goes through all essential requirements as listed in Annex I of the MDD. Please don't get confused: Contrary to all other templates here, quoted regions below (like this one) don't contain explanations (like this one), but instead actually quote the relevant section of the MDD. So, the legalese below is not me explaining stuff to you - it's the MDD.

Underneath each requirement, you determine whether it's applicable to your product. I've pre-filled it, making a few assumptions for software. But you should definitely go through all of them, just to make sure, e.g., 10 (do you have a measuring function?) and 12.4 (are you monitoring clinical parameters of patients?). Good luck.

1

The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report), Clinical Evaluation

This shall include reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report), IEC 62366-1:2015 (Usability Evaluation Report)

and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

- **Applicable:** Yes
- **Evidence of Conformity:** IEC 62366-1:2015 (Usability Evaluation Report)

2

The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- Eliminate or reduce risks as far as possible (inherently safe design and construction),
- Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- Inform users of the residual risks due to any shortcomings of the protection measures adopted.

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report)

3

The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

- **Applicable:** Yes
- **Evidence of Conformity:** IEC 62304:2006 (Software Verification), Clinical Evaluation

4

The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report), IEC 62304:2006 (Software Verification & Validation)

5

The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage

taking account of the instructions and information provided by the manufacturer.

- **Applicable:** No

6

Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report)

6a

Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

- **Applicable:** Yes
- **Evidence of Conformity:** Clinical Evaluation

7: Chemical, physical and biological properties

- **Applicable:** No

8: Infection and microbial contamination

- **Applicable:** No

9.1

If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report)

9.2

Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:

- The risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appro- priate ergonomic features,

- The risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
- The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
- The risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

- **Applicable:** No

9.3

Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in a single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

- **Applicable:** No

10: Devices with a measuring function

- **Applicable:** No

11: Protection against radiation

- **Applicable:** No

12.1

Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.

- **Applicable:** Yes

12.1a

For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

- **Applicable:** Yes

- **Evidence of Conformity:** ISO 14971:2019 (Risk Management Report), IEC 62304:2006 (SOP Software Development, Software Verification & Validation), IEC 62366-1:2015 (Usability Evaluation Report)

12.2 - 12.3

- **Applicable:** No

12.4

> Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

- **Applicable:** No (no monitoring)

12.5 - 12.8

- **Applicable:** No

13 Information supplied by the manufacturer

- **Applicable:** Yes
- **Evidence of Conformity:** ISO 14971:2019, IEC 62366-1:2015 (Labelling, Instructions for Use)
