

ESSENTIAL REQUIREMENTS CHECKLIST - MEDICAL DEVICE DEFECTIVE 9342/EC

COMPANY:

PRODUCT:

| Essential Requirement | A - N/A | Standards / References | Manufacturers Compliance / Notes / Explanation | Location |
|---|---------|------------------------|--|----------|
| <p>1. GENERAL PRINCIPLES</p> <p>1. The device 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, when 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.</p> <p>This shall include:</p> <ul style="list-style-type: none"> - selecting, as far as possible, the state of use, which due to the systematic failures of the device and the environment in which the device is intended to be used, design for patient safety, and - consideration of the technical knowledge, experience, education and training and when applicable the medical and physical conditions of intended users/design for lay professional, disabled or other users. | | | | |
| <p>2. The criteria adopted by the manufacturer for the design and construction of the device must conform to safety principles, taking account of the generally acknowledged state of the art.</p> <p>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:</p> <ul style="list-style-type: none"> - eliminate or reduce risks as far as possible inherently with design and construction - where appropriate take adequate protective measures (including where if necessary, to reduce or reduce the space by clearance, - reduce some of the residual risks due to any shortcomings of the protection methods adopted. | | | | |
| <p>3. The device must adhere to the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for use in order of the following order:</p> | | | | |
| <p>1. The characteristics and performance intended to be achieved in accordance with the standards referred to in Annex 1, 2 and 3 must not be adversely affected in such a degree that the clinical condition and safety of the patients and, when applicable, of other persons are compromised during the lifetime of the device as intended by the manufacturer, when the device is subjected to the stresses which are likely to be encountered under conditions of use.</p> | | | | |
| <p>2. The device must be designed, manufactured and packed in such a way that the characteristics and performance during their intended use will not be adversely affected during transport and storage taking account of the environmental and administrative conditions to be encountered.</p> | | | | |
| <p>3. Any acceptable risks which may constitute an acceptable risk when weighed against the performance intended.</p> | | | | |
| <p>4. Documentation of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 2.</p> | | | | |

Prepared by Anne Jury Associates

This document is meant purely as a documented tool and Anne Jury Associates do not assume any liability for its contents.

Revised to include all amendments up to and including Directive 2007/47/EC

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Iom Communications, Tuba Yamac

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




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