

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 set for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or other applicable stakeholders, 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, with due to the systematic features 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 business enterprise to which it is intended to be supplied by the manufacturer.</p>				
<p>4. The characteristics and performance intended to be achieved in accordance with the standards referred to in clause 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>5. The device must be designed, constructed 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 business and information available to the manufacturer.</p>				
<p>6. Any acceptable risks which may constitute an acceptable risk when weighed against the performance intended.</p>				
<p>7. Documentation of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 2.</p>				

Prepared by Anne Jury Associates

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

Essential Requirements Checklist Medical Device

Ian Pickup



Essential Requirements Checklist Medical Device:

Decoding **Essential Requirements Checklist Medical Device**: Revealing the Captivating Potential of Verbal Expression

In a period characterized by interconnectedness and an insatiable thirst for knowledge, the captivating potential of verbal expression has emerged as a formidable force. Its ability to evoke sentiments, stimulate introspection, and incite profound transformations is genuinely awe-inspiring. Within the pages of "**Essential Requirements Checklist Medical Device**," a mesmerizing literary creation penned with a celebrated wordsmith, readers embark on an enlightening odyssey, unraveling the intricate significance of language and its enduring effect on our lives. In this appraisal, we shall explore the book's central themes, evaluate its distinctive writing style, and gauge its pervasive influence on the hearts and minds of its readership.

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as a photographer who straddled the gap between art and commerce helmut newton always managed to surprise and polarize his audience among the editorial staff of many magazines he encountered creative kindred spirits who responded to his unusual visual ideas

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over 300 works based on the original polaroids were shown at 2011 exhibition helmut newton polaroids at the museum für fotografie in berlin 13 death edit

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throughout his career helmut newton used polaroids as both a crucial tool for testing light and composition and a means of revisiting his shoots these objects allow the viewer a rare chance to look behind the scenes of some of his greatest pictures from milan to paris and saint tropez

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jun 10 2011 helmut newton polaroids 10 06 2011 to 20 05 2012 museum für fotografie polaroid technology revolutionized photography polaroids have been used in artistic and commercial photography both in creating preliminary studies and as a medium in their own right

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mit helmut newton polaroids präsentiert die helmut newton stiftung erstmalig den werkaspekt der sofortbild fotografie im schaffen des fotografen und widmet ihm anhand von über 300 fotografien vergrößerungen der original polaroids ergänzt durch vitrinen mit den kleinformaten eine eigene ausstellung

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helmut newton also loved taking photographs with a polaroid from the 1970s onwards he used these devices extensively particularly during his fashion shoots so this exhibition does not just feature the polaroids of helmut newton but also works by numerous colleagues such as robert mapplethorpe mary ellen mark david hockney ulay

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