

## ESSENTIAL REQUIREMENTS CHECKLIST - MEDICAL DEVICE DEFECTIVE 9342/EC

COMPANY:

PRODUCT:

Essential Requirement	A - N/A	Standards / References	Manufacturers Compliance / Notes / Explanation	Location
<p><b>1. GENERAL PRINCIPLES</b></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, 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"> <li>- 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</li> <li>- 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).</li> </ul>				
<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"> <li>- eliminate or reduce risks as far as possible inherently with design and construction</li> <li>- where appropriate take adequate protective measures (including where if necessary, to reduce or reduce the space by clearance,</li> <li>- reduce some of the residual risks due to any shortcomings of the protection methods adopted.</li> </ul>				
<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 functions intended to be able to be used as specified by the manufacturer.</p>				
<p>4. The characteristics and performance intended to be achieved in accordance with the standards referred to in clauses 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, 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 instructions and information available to the user/owners.</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

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

# Essential Requirements Checklist Medical Device

**John G. Webster**



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## **Table of Contents Essential Requirements Checklist Medical Device**

1. Understanding the eBook Essential Requirements Checklist Medical Device
  - The Rise of Digital Reading Essential Requirements Checklist Medical Device
  - Advantages of eBooks Over Traditional Books
2. Identifying Essential Requirements Checklist Medical Device
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Essential Requirements Checklist Medical Device
  - User-Friendly Interface
4. Exploring eBook Recommendations from Essential Requirements Checklist Medical Device
  - Personalized Recommendations
  - Essential Requirements Checklist Medical Device User Reviews and Ratings

- Essential Requirements Checklist Medical Device and Bestseller Lists
- 5. Accessing Essential Requirements Checklist Medical Device Free and Paid eBooks
  - Essential Requirements Checklist Medical Device Public Domain eBooks
  - Essential Requirements Checklist Medical Device eBook Subscription Services
  - Essential Requirements Checklist Medical Device Budget-Friendly Options
- 6. Navigating Essential Requirements Checklist Medical Device eBook Formats
  - ePub, PDF, MOBI, and More
  - Essential Requirements Checklist Medical Device Compatibility with Devices
  - Essential Requirements Checklist Medical Device Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Essential Requirements Checklist Medical Device
  - Highlighting and Note-Taking Essential Requirements Checklist Medical Device
  - Interactive Elements Essential Requirements Checklist Medical Device
- 8. Staying Engaged with Essential Requirements Checklist Medical Device
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Essential Requirements Checklist Medical Device
- 9. Balancing eBooks and Physical Books Essential Requirements Checklist Medical Device
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Essential Requirements Checklist Medical Device
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Essential Requirements Checklist Medical Device
  - Setting Reading Goals Essential Requirements Checklist Medical Device
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Essential Requirements Checklist Medical Device
  - Fact-Checking eBook Content of Essential Requirements Checklist Medical Device
  - Distinguishing Credible Sources

13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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