MDR Database - MDRQ #1691

MDRQ # 1690 (Released): ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I GENERAL REQUIREMENTS

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Status:	Released	
Priority:	Low	

Description

CHAPTER I GENERAL REQUIREMENTS

Subissues:

MDRQ # 1692: 1. Devices shall achieve the performance intended by their manufacturer an...	**Released**
MDRQ # 1693: They shall be safe and effective and shall not compromise the clinical con...	**Released**
MDRQ # 1694: 2. The requirement in this Annex to reduce risks as far as possible means ...	**Released**
MDRQ # 1695: 3. Manufacturers shall establish, implement, document and maintain a risk ...	**Released**
MDRQ # 1696: Risk management shall be understood as a continuous iterative process thro...	**Released**
MDRQ # 1697: In carrying out risk management manufacturers shall:	**Released**
MDRQ # 1698: (a) establish and document a risk management plan for each device;	**Released**
MDRQ # 1699: (b) identify and analyse the known and foreseeable hazards associated with...	**Released**
MDRQ # 1700: (c) estimate and evaluate the risks associated with, and occurring during,...	**Released**
MDRQ # 1701: (d) eliminate or control the risks referred to in point (c) in accordance ...	**Released**
MDRQ # 1702: (e) evaluate the impact of information from the production phase and, in p...	**Released**
MDRQ # 1703: (f) based on the evaluation of the impact of the information referred to i...	**Released**
MDRQ # 1704: 4. Risk control measures adopted by manufacturers for the design and manuf...	**Released**
MDRQ # 1705: To reduce risks, Manufacturers shall manage risks so that the residual ris...	**Released**
MDRQ # 1706: In selecting the most appropriate solutions, manufacturers shall, in the f...	**Released**
MDRQ # 1707: (a) eliminate or reduce risks as far as possible through safe design and m...	**Released**
MDRQ # 1708: (b) where appropriate, take adequate protection measures, including alarms...	**Released**
MDRQ # 1709: (c) provide information for safety (warnings/precautions/contra-indication...	**Released**
MDRQ # 1710: Manufacturers shall inform users of any residual risks.	**Released**
MDRQ # 1711: 5. In eliminating or reducing risks related to use error, the manufacturer...	**Released**
MDRQ # 1712: (a) reduce as far as possible the risks related to the ergonomic features ...	**Released**
MDRQ # 1713: (b) give consideration to the technical knowledge, experience, education, ...	**Released**
MDRQ # 1714: 6. The characteristics and performance of a device shall not be adversely ...	**Released**
MDRQ # 1715: 7. Devices shall be designed, manufactured and packaged in such a way that...	**Released**
MDRQ # 1716: 8. All known and foreseeable risks, and any undesirable side-effects, shal...	**Released**
MDRQ # 1717: 9. For the devices referred to in Annex XVI, the general safety requiremen...	**Released**