MDR Database - MDRQ #1690

ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

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Status:	Released	
Priority:	Low	

Description

ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Subissues:

MDRQ # 1691: CHAPTER I GENERAL REQUIREMENTS	**Released**
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**
MDRQ # 1718: CHAPTER II REQUIREMENTS REGARDING DESIGN AND MANUFACTURE	**Released**
MDRQ # 1719: 10. Chemical, physical and biological properties	**Released**
MDRQ # 1720: 10.1. Devices shall be designed and manufactured in such a way as to ensur...	**Released**
MDRQ # 1721: Particular attention shall be paid to:	**Released**
MDRQ # 1722: (a) the choice of materials and substances used, particularly as regards t...	**Released**
MDRQ # 1723: (b) the compatibility between the materials and substances used and biolog...	**Released**
MDRQ # 1724: (c) the compatibility between the different parts of a device which consis...	**Released**
MDRQ # 1725: (d) the impact of processes on material properties;	**Released**
MDRQ # 1726: (e) where appropriate, the results of biophysical or modelling research th...	**Released**
MDRQ # 1727: (f) the mechanical properties of the materials used, reflecting, where app...	**Released**
MDRQ # 1728: (g) surface properties; and	**Released**
MDRQ # 1729: (h) the confirmation that the device meets any defined chemical and/or phy...	**Released**
MDRQ # 1730: 10.2. Devices shall be designed, manufactured and packaged in such a way a...	**Released**
MDRQ # 1731: Particular attention shall be paid to tissues exposed to those contaminant...	**Released**
MDRQ # 1732: 10.3. Devices shall be designed and manufactured in such a way that they c...	**Released**
MDRQ # 1733: 10.4. Substances	**Released**

MDRQ # 1734: 10.4.1. Design and manufacture of devices	**Released**
MDRQ # 1735: Devices shall be designed and manufactured in such a way as to reduce as f...	**Released**
MDRQ # 1736: Devices, or those parts thereof or those materials used therein that:	**Released**
MDRQ # 1737: ' are invasive and come into direct contact with the human body,	**Released**
MDRQ # 1738: ' (re)administer medicines, body liquids or other substances, including ga...	**Released**
MDRQ # 1739: ' transport or store such medicines, body fluids or substances, including ...	**Released**
MDRQ # 1740: shall only contain the following substances in a concentration that is abo...	**Released**
MDRQ # 1741: (a) substances which are carcinogenic, mutagenic or toxic to reproduction ...	**Released**
MDRQ # 1742: (b) substances having endocrine-disrupting properties for which there is s...	**Released**
MDRQ # 1743: 10.4.2. Justification regarding the presence of CMR and/or endocrine-disru...	**Released**
MDRQ # 1744: The justification for the presence of such substances shall be based upon:	**Released**
MDRQ # 1745: (a) an analysis and estimation of potential patient or user exposure to th...	**Released**
MDRQ # 1746: (b) an analysis of possible alternative substances, materials or designs, ...	**Released**
MDRQ # 1747: (c) argumentation as to why possible substance and/ or material substitute...	**Released**
MDRQ # 1748: (d) where applicable and available, the latest relevant scientific committ...	**Released**
MDRQ # 1749: 10.4.3. Guidelines on phthalates	**Released**
MDRQ # 1750: For the purposes of Section 10.4., the Commission shall, as soon as possib...	**Released**
MDRQ # 1751: The mandate for the committee shall encompass at least a benefit-risk asse...	**Released**
MDRQ # 1752: The benefit-risk assessment shall take into account the intended purpose a...	**Released**
MDRQ # 1753: When deemed appropriate on the basis of the latest scientific evidence, bu...	**Released**
MDRQ # 1754: 10.4.4. Guidelines on other CMR and endocrine-disrupting substances	**Released**
MDRQ # 1755: Subsequently, the Commission shall mandate the relevant scientific committ...	**Released**
MDRQ # 1756: 10.4.5. Labelling	**Released**
MDRQ # 1757: Where devices, parts thereof or materials used therein as referred to in S...	**Released**
MDRQ # 1758: If the intended use of such devices includes treatment of children or trea...	**Released**
MDRQ # 1759: 10.5. Devices shall be designed and manufactured in such a way as to reduc...	**Released**
MDRQ # 1760: 10.6. Devices shall be designed and manufactured in such a way as to reduc...	**Released**
MDRQ # 1761: Special attention shall be given to nanomaterials.	**Released**
MDRQ # 1762: 11. Infection and microbial contamination	**Released**
MDRQ # 1763: 11.1. Devices and their manufacturing processes shall be designed in such ...	**Released**
MDRQ # 1764: The design shall:	**Released**
MDRQ # 1765: (a) reduce as far as possible and appropriate the risks from unintended cu...	**Released**
MDRQ # 1766: (b) allow easy and safe handling,	**Released**
MDRQ # 1767: (c) reduce as far as possible any microbial leakage from the device and/or...	**Released**
MDRQ # 1768: (d) prevent microbial contamination of the device or its content such as s...	**Released**
MDRQ # 1769: 11.2. Where necessary devices shall be designed to facilitate their safe c...	**Released**
MDRQ # 1770: 11.3. Devices labelled as having a specific microbial state shall be desig...	**Released**
MDRQ # 1771: 11.4. Devices delivered in a sterile state shall be designed, manufactured...	**Released**
MDRQ # 1772: It shall be ensured that the integrity of that packaging is clearly eviden...	**Released**
MDRQ # 1773: 11.5. Devices labelled as sterile shall be processed, manufactured, packag...	**Released**
MDRQ # 1774: 11.6. Devices intended to be sterilised shall be manufactured and packaged...	**Released**
MDRQ # 1775: 11.7. Packaging systems for non-sterile devices shall maintain the integri...	**Released**
MDRQ # 1776: 11.8. The labelling of the device shall distinguish between identical or s...	**Released**
MDRQ # 1777: 12. Devices incorporating a substance considered to be a medicinal product...	**Released**
MDRQ # 1778: 12.1. In the case of devices referred to in the first subparagraph of Arti...	**Released**
MDRQ # 1779: 12.2. Devices that are composed of substances or of combinations of substa...	**Released**
MDRQ # 1780: 13. Devices incorporating materials of biological origin	**Released**
MDRQ # 1781: 13.1. For devices manufactured utilising derivatives of tissues or cells o...	**Released**
MDRQ # 1782: (a) donation, procurement and testing of the tissues and cells shall be do...	**Released**
MDRQ # 1783: (b) processing, preservation and any other handling of those tissues and c...	**Released**
MDRQ # 1784: In particular, safety with regard to viruses and other transmissible agent...	**Released**
MDRQ # 1785: (c) the traceability system for those devices shall be complementary and c...	**Released**
MDRQ # 1786: 13.2. For devices manufactured utilising tissues or cells of animal origin...	**Released**

MDRQ # 1787: (a) where feasible taking into account the animal species, tissues and cel...	**Released**
MDRQ # 1788: Information on the geographical origin of the animals shall be retained by...	**Released**
MDRQ # 1789: (b) sourcing, processing, preservation, testing and handling of tissues, c...	**Released**
MDRQ # 1790: In particular safety with regard to viruses and other transmissible agents...	**Released**
MDRQ # 1791: (c) in the case of devices manufactured utilising tissues or cells of anim...	**Released**
MDRQ # 1792: 13.3. For devices manufactured utilising non-viable biological substances ...	**Released**
MDRQ # 1793: In particular, safety with regard to viruses and other transmissible agent...	**Released**
MDRQ # 1794: 14. Construction of devices and interaction with their environment	**Released**
MDRQ # 1795: 14.1. If the device is intended for use in combination with other devices ...	**Released**
MDRQ # 1796: Any restrictions on use applying to such combinations shall be indicated o...	**Released**
MDRQ # 1797: Connections which the user has to handle, such as fluid, gas transfer, ele...	**Released**
MDRQ # 1798: 14.2. Devices shall be designed and manufactured in such a way as to remov...	**Released**
MDRQ # 1799: (a) the risk of injury, in connection with their physical features, includ...	**Released**
MDRQ # 1800: (b) risks connected with reasonably foreseeable external influences or env...	**Released**
MDRQ # 1801: (c) the risks associated with the use of the device when it comes into con...	**Released**
MDRQ # 1802: (d) the risks associated with the possible negative interaction between so...	**Released**
MDRQ # 1803: (e) the risks of accidental ingress of substances into the device;	**Released**
MDRQ # 1804: (f) the risks of reciprocal interference with other devices normally used ...	**Released**
MDRQ # 1805: (g) risks arising where maintenance or calibration are not possible (as wi...	**Released**
MDRQ # 1806: 14.3. Devices shall be designed and manufactured in such a way as to minim...	**Released**
MDRQ # 1807: Particular attention shall be paid to devices the intended use of which in...	**Released**
MDRQ # 1808: 14.4. Devices shall be designed and manufactured in such a way that adjust...	**Released**
MDRQ # 1809: 14.5. Devices that are intended to be operated together with other devices...	**Released**
MDRQ # 1810: 14.6 Any measurement, monitoring or display scale shall be designed and ma...	**Released**
MDRQ # 1811: 14.7. Devices shall be designed and manufactured in such a way as to facil...	**Released**
MDRQ # 1812: To that end, manufacturers shall identify and test procedures and measures...	**Released**
MDRQ # 1813: Such procedures shall be described in the instructions for use.	**Released**
MDRQ # 1814: 15. Devices with a diagnostic or measuring function	**Released**
MDRQ # 1815: 15.1. Diagnostic devices and devices with a measuring function, shall be d...	**Released**
MDRQ # 1816: The limits of accuracy shall be indicated by the manufacturer.	**Released**
MDRQ # 1817: 15.2. The measurements made by devices with a measuring function shall be ...	**Released**
MDRQ # 1818: 16. Protection against radiation	**Released**
MDRQ # 1819: 16.1. General	**Released**
MDRQ # 1820: (a) Devices shall be designed, manufactured and packaged in such a way tha...	**Released**
MDRQ # 1821: (b) The operating instructions for devices emitting hazardous or potential...	**Released**
MDRQ # 1822: Information regarding the acceptance and performance testing, the acceptan...	**Released**
MDRQ # 1823: 16.2. Intended radiation	**Released**
MDRQ # 1824: (a) Where devices are designed to emit hazardous, or potentially hazardous...	**Released**
MDRQ # 1825: Such devices shall be designed and manufactured to ensure reproducibility ...	**Released**
MDRQ # 1826: (b) Where devices are intended to emit hazardous, or potentially hazardous...	**Released**
MDRQ # 1827: 16.3. Devices shall be designed and manufactured in such a way that exposu...	**Released**
MDRQ # 1828: Where possible and appropriate, methods shall be selected which reduce the...	**Released**
MDRQ # 1829: 16.4. Ionising radiation	**Released**
MDRQ # 1830: (a) Devices intended to emit ionizing radiation shall be designed and manu...	**Released**
MDRQ # 1831: (b) Devices intended to emit ionising radiation shall be designed and manu...	**Released**
MDRQ # 1832: (c) Devices emitting ionising radiation intended for diagnostic radiology ...	**Released**
MDRQ # 1833: (d) Devices that emit ionising radiation and are intended for therapeutic ...	**Released**
MDRQ # 1834: 17. Electronic programmable systems ' devices that incorporate electronic ...	**Released**
MDRQ # 1835: 17.1. Devices that incorporate electronic programmable systems, including ...	**Released**
MDRQ # 1836: In the event of a single fault condition, appropriate means shall be adopt...	**Released**
MDRQ # 1837: 17.2. For devices that incorporate software or for software that are devic...	**Released**
MDRQ # 1838: 17.3. Software referred to in this Section that is intended to be used in ...	**Released**
MDRQ # 1839: 17.4. Manufacturers shall set out minimum requirements concerning hardware...	**Released**

MDRQ # 1840: 18. Active devices and devices connected to them	**Released**
MDRQ # 1841: 18.1. For non-implantable active devices, in the event of a single fault c...	**Released**
MDRQ # 1842: 18.2. Devices where the safety of the patient depends on an internal power...	**Released**
MDRQ # 1843: If necessary, such warning or indication shall be given prior to the power...	**Released**
MDRQ # 1844: 18.3. Devices where the safety of the patient depends on an external power...	**Released**
MDRQ # 1845: 18.4. Devices intended to monitor one or more clinical parameters of a pat...	**Released**
MDRQ # 1846: 18.5. Devices shall be designed and manufactured in such a way as to reduc...	**Released**
MDRQ # 1847: 18.6. Devices shall be designed and manufactured in such a way as to provi...	**Released**
MDRQ # 1848: 18.7. Devices shall be designed and manufactured in such a way as to avoid...	**Released**
MDRQ # 1849: 18.8. Devices shall be designed and manufactured in such a way as to prote...	**Released**
MDRQ # 1850: 19. Particular requirements for active implantable devices	**Released**
MDRQ # 1851: 19.1. Active implantable devices shall be designed and manufactured in suc...	**Released**
MDRQ # 1852: (a) risks connected with the use of energy sources with particular referen...	**Released**
MDRQ # 1853: (b) risks connected with medical treatment, in particular those resulting ...	**Released**
MDRQ # 1854: (c) risks which may arise where maintenance and calibration are impossible...	**Released**
MDRQ # 1855: 19.2. Active implantable devices shall be designed and manufactured in suc...	**Released**
MDRQ # 1856: ' if applicable, the compatibility of the devices with the substances they...	**Released**
MDRQ # 1857: ' the reliability of the source of energy.	**Released**
MDRQ # 1858: 19.3. Active implantable devices and, if appropriate, their component part...	**Released**
MDRQ # 1859: 19.4. Active implantable devices shall bear a code by which they and their...	**Released**
MDRQ # 1860: 20. Protection against mechanical and thermal risks	**Released**
MDRQ # 1861: 20.1. Devices shall be designed and manufactured in such a way as to prote...	**Released**
MDRQ # 1862: 20.2. Devices shall be designed and manufactured in such a way as to reduc...	**Released**
MDRQ # 1863: 20.3. Devices shall be designed and manufactured in such a way as to reduc...	**Released**
MDRQ # 1864: 20.4. Terminals and connectors to the electricity, gas or hydraulic and pn...	**Released**
MDRQ # 1865: 20.5. Errors likely to be made when fitting or refitting certain parts whi...	**Released**
MDRQ # 1866: The same information shall be given on moving parts and/or their housings ...	**Released**
MDRQ # 1867: 20.6. Accessible parts of devices (excluding the parts or areas intended t...	**Released**
MDRQ # 1868: 21. Protection against the risks posed to the patient or user by devices s...	**Released**
MDRQ # 1869: 21.1. Devices for supplying the patient with energy or substances shall be...	**Released**
MDRQ # 1870: 21.2. Devices shall be fitted with the means of preventing and/or indicati...	**Released**
MDRQ # 1871: Devices shall incorporate suitable means to prevent, as far as possible, t...	**Released**
MDRQ # 1872: 21.3. The function of the controls and indicators shall be clearly specifi...	**Released**
MDRQ # 1873: Where a device bears instructions required for its operation or indicates ...	**Released**
MDRQ # 1874: 22. Protection against the risks posed by medical devices intended by the ...	**Released**
MDRQ # 1875: 22.1. Devices for use by lay persons shall be designed and manufactured in...	**Released**
MDRQ # 1876: The information and instructions provided by the manufacturer shall be eas...	**Released**
MDRQ # 1877: 22.2. Devices for use by lay persons shall be designed and manufactured in...	**Released**
MDRQ # 1878: ' ensure that the device can be used safely and accurately by the intended...	**Released**
MDRQ # 1879: ' reduce, as far as possible and appropriate, the risk from unintended cut...	**Released**
MDRQ # 1880: ' reduce as far as possible the risk of error by the intended user in the ...	**Released**
MDRQ # 1881: 22.3. Devices for use by lay persons shall, where appropriate, include a p...	**Released**
MDRQ # 1882: ' can verify that, at the time of use, the device will perform as intended...	**Released**
MDRQ # 1883: ' if applicable, is warned if the device has failed to provide a valid res...	**Released**
MDRQ # 1884: CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE	**Released**
MDRQ # 1885: 23. Label and instructions for use	**Released**
MDRQ # 1886: 23.1. General requirements regarding the information supplied by the manuf...	**Released**
MDRQ # 1887: Each device shall be accompanied by the information needed to identify the...	**Released**
MDRQ # 1888: Such information may appear on the device itself, on the packaging or in t...	**Released**
MDRQ # 1889: (a) The medium, format, content, legibility, and location of the label and...	**Released**
MDRQ # 1890: In particular, instructions for use shall be written in terms readily unde...	**Released**
MDRQ # 1891: (b) The information required on the label shall be provided on the device ...	**Released**
MDRQ # 1892: If this is not practicable or appropriate, some or all of the information ...	**Released**

MDRQ # 1893: (c) Labels shall be provided in a human-readable format and may be supplem...	**Released**
MDRQ # 1894: (d) Instructions for use shall be provided together with devices.	**Released**
MDRQ # 1895: By way of exception, instructions for use shall not be required for class ...	**Released**
MDRQ # 1896: (e) Where multiple devices are supplied to a single user and/or location, ...	**Released**
MDRQ # 1897: (f) Instructions for use may be provided to the user in non-paper format (...	**Released**
MDRQ # 1898: (g) Residual risks which are required to be communicated to the user and/o...	**Released**
MDRQ # 1899: (h) Where appropriate, the information supplied by the manufacturer shall ...	**Released**
MDRQ # 1900: Any symbol or identification colour used shall conform to the harmonised s...	**Released**
MDRQ # 1901: In areas for which no harmonised standards or CS exist, the symbols and co...	**Released**
MDRQ # 1902: 23.2. Information on the label	**Released**
MDRQ # 1903: The label shall bear all of the following particulars:	**Released**
MDRQ # 1904: (a) the name or trade name of the device;	**Released**
MDRQ # 1905: (b) the details strictly necessary for a user to identify the device, the ...	**Released**
MDRQ # 1906: (c) the name, registered trade name or registered trade mark of the manufa...	**Released**
MDRQ # 1907: (d) if the manufacturer has its registered place of business outside the U...	**Released**
MDRQ # 1908: (e) where applicable, an indication that the device contains or incorporat...	**Released**
MDRQ # 1909: (f) where applicable, information labelled in accordance with Section 10.4...	**Released**
MDRQ # 1910: (g) the lot number or the serial number of the device preceded by the word...	**Released**
MDRQ # 1911: (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VII;	**Released**
MDRQ # 1912: (i) an unambiguous indication of t the time limit for using or implanting ...	**Released**
MDRQ # 1913: (j) where there is no indication of the date until when it may be used saf...	**Released**
MDRQ # 1914: This date of manufacture may be included as part of the lot number or seri...	**Released**
MDRQ # 1915: (k) an indication of any special storage and/or handling condition that ap...	**Released**
MDRQ # 1916: (l) if the device is supplied sterile, an indication of its sterile state ...	**Released**
MDRQ # 1917: (m) warnings or precautions to be taken that need to be brought to the imm...	**Released**
MDRQ # 1918: This information may be kept to a minimum in which case more detailed info...	**Released**
MDRQ # 1919: (n) if the device is intended for single use, an indication of that fact.	**Released**
MDRQ # 1920: A manufacturer's indication of single use shall be consistent across the U...	**Released**
MDRQ # 1921: (o) if the device is a single-use device that has been reprocessed, an ind...	**Released**
MDRQ # 1922: (p) if the device is custom-made, the words 'custom-made device';	**Released**
MDRQ # 1923: (q) an indication that the device is a medical device.	**Released**
MDRQ # 1924: If the device is intended for clinical investigation only, the words 'excl...	**Released**
MDRQ # 1925: (r) in the case of devices that are composed of substances or of combinati...	**Released**
MDRQ # 1926: (s) for active implantable devices, the serial number, and for other impla...	**Released**
MDRQ # 1927: 23.3. Information on the packaging which maintains the sterile condition o...	**Released**
MDRQ # 1928: The following particulars shall appear on the sterile packaging:	**Released**
MDRQ # 1929: (a) an indication permitting the sterile packaging to be recognised as such,	**Released**
MDRQ # 1930: (b) a declaration that the device is in a sterile condition,	**Released**
MDRQ # 1931: (c) the method of sterilisation,	**Released**
MDRQ # 1932: (d) the name and address of the manufacturer,	**Released**
MDRQ # 1933: (e) a description of the device,	**Released**
MDRQ # 1934: (f) if the device is intended for clinical investigations, the words 'excl...	**Released**
MDRQ # 1935: (g) if the device is custom-made, the words 'custom-made device',	**Released**
MDRQ # 1936: (h) the month and year of manufacture,	**Released**
MDRQ # 1937: (i) an unambiguous indication of the time limit for using or implanting th...	**Released**
MDRQ # 1938: (j) an instruction to check the instructions for use for what to do if the...	**Released**
MDRQ # 1939: 23.4. Information in the instructions for use	**Released**
MDRQ # 1940: The instructions for use shall contain all of the following particulars:	**Released**
MDRQ # 1941: (a) the particulars referred to in points (a), (c), (e), (f), (k), (l), (n...	**Released**
MDRQ # 1942: (b) the device's intended purpose with a clear specification of indication...	**Released**
MDRQ # 1943: (c) where applicable, a specification of the clinical benefits to be expec...	**Released**
MDRQ # 1944: (d) where applicable, links to the summary of safety and clinical performa...	**Released**
MDRQ # 1945: (e) the performance characteristics of the device;	**Released**

MDRQ # 1946: (f) where applicable, information allowing the healthcare professional to ...	**Released**
MDRQ # 1947: (g) any residual risks, contra-indications and any undesirable side-effect...	**Released**
MDRQ # 1948: (h) specifications the user requires to use the device appropriately, e.g....	**Released**
MDRQ # 1949: (i) details of any preparatory treatment or handling of the device before ...	**Released**
MDRQ # 1950: (j) any requirements for special facilities, or special training, or parti...	**Released**
MDRQ # 1951: (k) the information needed to verify whether the device is properly instal...	**Released**
MDRQ # 1952: (l) if the device is supplied sterile, instructions in the event of the st...	**Released**
MDRQ # 1953: (m) if the device is supplied non-sterile with the intention that it is st...	**Released**
MDRQ # 1954: (n) if the device is reusable, information on the appropriate processes fo...	**Released**
MDRQ # 1955: Information shall be provided to identify when the device should no longer...	**Released**
MDRQ # 1956: (o) an indication, if appropriate, that a device can be reused only if it ...	**Released**
MDRQ # 1957: (p) if the device bears an indication that it is for single use, informati...	**Released**
MDRQ # 1958: This information shall be based on a specific section of the manufacturer'...	**Released**
MDRQ # 1959: If in accordance with point (d) of Section 23.1. no instructions for use a...	**Released**
MDRQ # 1960: (q) for devices intended for use together with other devices and/or genera...	**Released**
MDRQ # 1961: (r) if the device emits radiation for medical purposes: ' detailed informa...	**Released**
MDRQ # 1962: (s) information that allows the user and/or patient to be informed of any ...	**Released**
MDRQ # 1963: That information shall, where relevant, allow the user to brief the patien...	**Released**
MDRQ # 1964: The information shall cover, where appropriate: ' warnings, precautions an...	**Released**
MDRQ # 1965: (t) in the case of devices that are composed of substances or of combinati...	**Released**
MDRQ # 1966: (u) in the case of implantable devices, the overall qualitative and quanti...	**Released**
MDRQ # 1967: (v) warnings or precautions to be taken in order to facilitate the safe di...	**Released**
MDRQ # 1968: This information shall cover, where appropriate: ' infection or microbial ...	**Released**
MDRQ # 1969: If in accordance with the point (d) of Section 23.1 no instructions for us...	**Released**
MDRQ # 1970: (w) for devices intended for use by lay persons, the circumstances in whic...	**Released**
MDRQ # 1971: (x) for the devices covered by this Regulation pursuant to Article 1(2), i...	**Released**
MDRQ # 1972: (y) date of issue of the instructions for use or, if they have been revise...	**Released**
MDRQ # 1973: (z) a notice to the user and/or patient that any serious incident that has...	**Released**
MDRQ # 1974: (aa) information to be supplied to the patient with an implanted device in...	**Released**
MDRQ # 1975: (ab) for devices that incorporate electronic programmable systems, includi...	**Released**
MDRQ # 1976: <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:320...	**Released**
MDRQ # 1977: <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:320...	**Released**
MDRQ # 1978: <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:320...	**Released**
MDRQ # 1979: <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:320...	**Released**