

MDR Database - MDRQ #2122

MDRQ # 2073 (Released): ANNEX VI INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLES 29(4) AND 31, CORE DATA ELEMENTS TO BE PROVIDED TO THE UDI DATABASE TOGETHER WITH THE UDI-DI IN ACCORDANCE WITH ARTICLES 28 AND 29, AND THE UDI SYSTEM

PART C: THE UDI SYSTEM

11/04/2017 02:19 PM - Anonymous

Status:	Released	
Priority:	Low	
Description		
PART C: THE UDI SYSTEM		
Subissues:		
MDRQ # 2123: 1. Definitions		Released
MDRQ # 2124: Automatic identification and data capture ('AIDC')		Released
MDRQ # 2125: AIDC is a technology used to automatically capture data.		Released
MDRQ # 2126: AIDC technologies include bar codes, smart cards, biometrics and RFID.		Released
MDRQ # 2127: Basic UDI-DI		Released
MDRQ # 2128: The Basic UDI-DI is the primary identifier of a device model.		Released
MDRQ # 2129: It is the DI assigned at the level of the device unit of use.		Released
MDRQ # 2130: It is the main key for records in the UDI database and is referenced in re...		Released
MDRQ # 2131: Unit of Use DI		Released
MDRQ # 2132: The Unit of Use DI serves to associate the use of a device with a patient ...		Released
MDRQ # 2133: Configurable device		Released
MDRQ # 2134: A configurable device is a device that consists of several components whic...		Released
MDRQ # 2135: Those individual components may be devices in themselves.		Released
MDRQ # 2136: Configurable devices include computed tomography (CT) systems, ultrasound ...		Released
MDRQ # 2137: Configuration		Released
MDRQ # 2138: Configuration is a combination of items of equipment, as specified by the ...		Released
MDRQ # 2139: The combination of items may be modified, adjusted or customized to meet s...		Released
MDRQ # 2140: Configurations include inter alia:		Released
MDRQ # 2141: ' gantries, tubes, tables, consoles and other items of equipment that can ...		Released
MDRQ # 2142: ' ventilators, breathing circuits, vaporizers combined to deliver an inten...		Released
MDRQ # 2143: UDI-DI		Released
MDRQ # 2144: The UDI-DI is a unique numeric or alphanumeric code specific to a model of...		Released
MDRQ # 2145: Human Readable Interpretation ('HRI')		Released
MDRQ # 2146: HRI is a legible interpretation of the data characters encoded in the UDI ...		Released
MDRQ # 2147: Packaging levels		Released
MDRQ # 2148: Packaging levels means the various levels of device packaging that contain...		Released
MDRQ # 2149: UDI-PI		Released
MDRQ # 2150: The UDI-PI is a numeric or alphanumeric code that identifies the unit of d...		Released
MDRQ # 2151: The different types of UDI-PIs include serial number, lot number, software...		Released
MDRQ # 2152: Radio Frequency Identification RFID		Released
MDRQ # 2153: RFID is a technology that uses communication through the use of radio wave...		Released
MDRQ # 2154: Shipping containers		Released
MDRQ # 2155: A shipping container is a container in relation to which traceability is c...		Released
MDRQ # 2156: Unique Device Identifier ('UDI')		Released
MDRQ # 2157: The UDI is a series of numeric or alphanumeric characters that is created ...		Released
MDRQ # 2158: It allows the unambiguous identification of a specific device on the market.		Released
MDRQ # 2159: The UDI is comprised of the UDI-DI and the UDI-PI.		Released
MDRQ # 2160: The word 'Unique' does not imply serialisation of individual production un...		Released
MDRQ # 2161: UDI carrier		Released
MDRQ # 2162: The UDI carrier is the means of conveying the UDI by using AIDC and, if ap...		Released

MDRQ # 2163: UDI carriers include, inter alia, ID/linear bar code, 2D/Matrix bar code, ...	Released
MDRQ # 2164: 2. General requirements	Released
MDRQ # 2165: 2.1. The affixing of the UDI is an additional requirement ' it does not re...	Released
MDRQ # 2166: 2.2. The manufacturer shall assign and maintain unique UDIs for its devices.	Released
MDRQ # 2167: 2.3. Only the manufacturer may place the UDI on the device or its packaging.	Released
MDRQ # 2168: 2.4. Only coding standards provided by issuing entities designated by the ...	Released
MDRQ # 2169: 3. The UDI	Released
MDRQ # 2170: 3.1. A UDI shall be assigned to the device itself or its packaging.	Released
MDRQ # 2171: Higher levels of packaging shall have their own UDI.	Released
MDRQ # 2172: 3.2. Shipping containers shall be exempted from the requirement in Section...	Released
MDRQ # 2173: By way of example, a UDI shall not be required on a logistics unit; where ...	Released
MDRQ # 2174: 3.3. The UDI shall contain two parts: a UDI-DI and a UDI-PI.	Released
MDRQ # 2175: 3.4. The UDI-DI shall be unique at each level of device packaging.	Released
MDRQ # 2176: 3.5. If a lot number, serial number, software identification or expiry dat...	Released
MDRQ # 2177: If there is also a manufacturing date on the label, it does not need to be...	Released
MDRQ # 2178: If there is only a manufacturing date on the label, this shall be used as ...	Released
MDRQ # 2179: 3.6. Each component that is considered to be a device and is commercially ...	Released
MDRQ # 2180: 3.7. Systems and procedure packs as referred to in Article 22 shall be ass...	Released
MDRQ # 2181: 3.8. The manufacturer shall assign the UDI to a device following the relev...	Released
MDRQ # 2182: 3.9. A new UDI-DI shall be required whenever there is a change that could ...	Released
MDRQ # 2183: a) name or trade name	Released
MDRQ # 2184: (b) device version or model,	Released
MDRQ # 2185: (c) labelled as single use,	Released
MDRQ # 2186: (e) need for sterilization before use,	Released
MDRQ # 2187: (f) quantity of devices provided in a package,	Released
MDRQ # 2188: (g) critical warnings or contra-indications: e.g. containing latex or DEHP.	Released
MDRQ # 2189: 3.10. Manufacturers that repackage and/or relabel devices, with their own ...	Released
MDRQ # 2190: 4. UDI carrier	Released
MDRQ # 2191: 4.1. The UDI carrier (AIDC and HRI representation of the UDI) shall be pla...	Released
MDRQ # 2192: Higher levels do not include shipping containers.	Released
MDRQ # 2193: 4.2. In the event of there being significant space constraints on the unit...	Released
MDRQ # 2194: 4.3. For single-use devices of classes I and IIa packaged and labelled ind...	Released
MDRQ # 2195: However, when the healthcare provider is not expected to have access, in c...	Released
MDRQ # 2196: 4.4. For devices exclusively intended for retail point of sale the UDI-PIs...	Released
MDRQ # 2197: 4.5. When AIDC carriers other than the UDI carrier are part of the product...	Released
MDRQ # 2198: 4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenat...	Released
MDRQ # 2199: All parts and elements of the linear bar code shall be distinguishable and...	Released
MDRQ # 2200: 4.7. If there are significant constraints limiting the use of both AIDC an...	Released
MDRQ # 2201: For devices intended to be used outside healthcare facilities, such as dev...	Released
MDRQ # 2202: 4.8. The HRI format shall follow the rules of the UDI code-issuing entity.	Released
MDRQ # 2203: 4.9. If the manufacturer is using RFID technology, a linear or 2D bar code...	Released
MDRQ # 2204: 4.10. Devices that are reusable shall bear a UDI carrier on the device its...	Released
MDRQ # 2205: The UDI carrier for reusable devices that require cleaning, disinfection, ...	Released
MDRQ # 2206: The requirement of this Section shall not apply to devices in the followin...	Released
MDRQ # 2207: (a) any type of direct marking would interfere with the safety or performa...	Released
MDRQ # 2208: (b) the device cannot be directly marked because it is not technologically...	Released
MDRQ # 2209: 4.11. The UDI carrier shall be readable during normal use and throughout t...	Released
MDRQ # 2210: 4.12. If the UDI carrier is readily readable or, in the case of AIDC, scan...	Released
MDRQ # 2211: 4.13. In the case of single finished devices made up of multiple parts tha...	Released
MDRQ # 2212: 4.14. The UDI carrier shall be placed in a manner such that the AIDC can b...	Released
MDRQ # 2213: 4.15. Bar code carriers that include both a UDI-DI and a UDI-PI may also i...	Released
MDRQ # 2214: 5. General principles of the UDI database	Released
MDRQ # 2215: 5.1. The UDI database shall support the use of all core UDI database data ...	Released

MDRQ # 2216: 5.2. Manufacturers shall be responsible for the initial submission and upd...	Released
MDRQ # 2217: 5.3. Appropriate methods/procedures for validation of the data provided sh...	Released
MDRQ # 2218: 5.4. Manufacturers shall periodically verify the correctness of all of the...	Released
MDRQ # 2219: 5.5. The presence of the device UDI-DI in the UDI database shall not be as...	Released
MDRQ # 2220: 5.6. The database shall allow for the linking of all the packaging levels ...	Released
MDRQ # 2221: 5.7. The data for new UDI-DIs shall be available at the time the device is...	Released
MDRQ # 2222: 5.8. Manufacturers shall update the relevant UDI database record within 30...	Released
MDRQ # 2223: 5.9. Internationally-accepted standards for data submission and updates sh...	Released
MDRQ # 2224: 5.10. The user interface of the UDI database shall be available in all off...	Released
MDRQ # 2225: The use of free-text fields shall, however, be minimized in order to reduc...	Released
MDRQ # 2226: 5.11. Data relating to devices that are no longer available on the market ...	Released
MDRQ # 2227: 6. Rules for specific device types	Released
MDRQ # 2228: 6.1. Implantable devices:	Released
MDRQ # 2229: 6.1.1. Implantable devices shall, at their lowest level of packaging ('uni...	Released
MDRQ # 2230: 6.1.2. The UDI-PI shall have at least the following characteristics: (a) t...	Released
MDRQ # 2231: 6.1.3. The UDI of the implantable device shall be identifiable prior to im...	Released
MDRQ # 2232: 6.2. Reusable devices requiring cleaning, disinfection, sterilisation or r...	Released
MDRQ # 2233: 6.2.1. The UDI of such devices shall be placed on the device and be readab...	Released
MDRQ # 2234: 6.2.2. The UDI-PI characteristics such as the lot or serial number shall b...	Released
MDRQ # 2235: 6.3. Systems and procedure packs as referred to in Article 22	Released
MDRQ # 2236: 6.3.1. The natural or legal person referred to in Article 22 shall be resp...	Released
MDRQ # 2237: 6.3.2. Device contents of system or procedure packs shall bear a UDI carri...	Released
MDRQ # 2238: Exemptions:	Released
MDRQ # 2239: (a) individual single-use disposable devices, the uses of which are genera...	Released
MDRQ # 2240: (b) devices that are exempted from bearing a UDI carrier on the relevant l...	Released
MDRQ # 2241: 6.3.3. Placement of the UDI carrier on systems or procedure packs	Released
MDRQ # 2242: (a) The system or procedure pack UDI carrier shall as a general rule be af...	Released
MDRQ # 2243: (b) The UDI carrier shall be readable, or, in the case of AIDC, scannable,...	Released
MDRQ # 2244: 6.4. Configurable devices:	Released
MDRQ # 2245: 6.4.1. A UDI shall be assigned to the configurable device in its entirety ...	Released
MDRQ # 2246: 6.4.2. The configurable device UDI-DI shall be assigned to groups of confi...	Released
MDRQ # 2247: A group of configurations is defined as the collection of possible configu...	Released
MDRQ # 2248: 6.4.3. A configurable device UDI-PI shall be assigned to each individual c...	Released
MDRQ # 2249: 6.4.4. The carrier of the configurable device UDI shall be placed on the a...	Released
MDRQ # 2250: 6.4.5. Each component that is considered a device and is commercially avai...	Released
MDRQ # 2251: 6.5. Device Software	Released
MDRQ # 2252: 6.5.1. UDI assignment Criteria	Released
MDRQ # 2253: The UDI shall be assigned at the system level of the software.	Released
MDRQ # 2254: Only software which is commercially available on its own and software whic...	Released
MDRQ # 2255: The software identification shall be considered to be the manufacturing co...	Released
MDRQ # 2256: 6.5.2. A new UDI-DI shall be required whenever there is a modification tha...	Released
MDRQ # 2257: (a) the original performance;	Released
MDRQ # 2258: (b) the safety or the intended use of the software;	Released
MDRQ # 2259: (c) interpretation of data.	Released
MDRQ # 2260: Such modifications include new or modified algorithms, database structures...	Released
MDRQ # 2261: 6.5.3. Minor software revisions shall require a new UDI-PI and not a new U...	Released
MDRQ # 2262: Minor software revisions are generally associated with bug fixes, usabilit...	Released
MDRQ # 2263: Minor software revisions shall be identified by a manufacturer-specific fo...	Released
MDRQ # 2264: 6.5.4. UDI placement criteria for software	Released
MDRQ # 2265: (a) where the software is delivered on a physical medium, e.g.	Released
MDRQ # 2266: CD or DVD, each packaging level shall bear the human readable and AIDC rep...	Released
MDRQ # 2267: The UDI that is applied to the physical medium containing the software and...	Released
MDRQ # 2268: (b) the UDI shall be provided on a readily accessible screen for the user ...	Released

MDRQ # 2269: (c) software lacking a user interface such as middleware for image convers...	Released
MDRQ # 2270: (d) only the human readable portion of the UDI shall be required in electr...	Released
MDRQ # 2271: The marking of UDI using AIDC shall not be required in the electronic disp...	Released
MDRQ # 2272: (e) the human readable format of the UDI for the software shall include th...	Released