

MDR Database - MDRQ #2187

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

MDRQ # 2122 (Released): PART C: THE UDI SYSTEM

MDRQ # 2169 (Released): 3. The UDI

MDRQ # 2182 (Released): 3.9. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability; in particular, any change of one of the following UDI database data elements shall require a new UDI-DI:

(f) quantity of devices provided in a package,

11/04/2017 02:19 PM - Anonymous

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| Status: | Released | |
| Priority: | Low | |
| Description | | |
| (f) quantity of devices provided in a package, | | |