Joint NB-Position Paper on Spinal Classification per the MDR

Content

1. Introduction

This document summarizes the opinion of NB-Med and Team-NB on rule 8 of the medical device regulation (EU) 2017/745. It was created to facilitate the discussion about the classification of implantable devices and long-term surgical invasive devices as described in the regulation and to ensure a harmonized implementation of the classification rules throughout Notified Bodies.

ANNEX VII - 5.4. - Rule 8 of the MDR includes for various neurosurgical implants unspecific wording which is not considering the establishment level of these devices and is leading to their up-classification to the highest risk class in Europe (Class III). Professional resources of a representative number of notified bodies met to clarify, discuss and agree on the interpretation of this new rule and communicate a common understanding back to the relevant EU authorities and if relevant the EU Commission.

The current position paper aims to provide a risk-based decision tree which considers the establishment level of the various devices, their clinical evidence and the risks associated with their usage.

2. Legal text: Specific wording in the MDR regarding spinal classification

2.1 ANNEX VIII 5.4. Rule 8

All implantable devices and long-term surgically invasive devices are in class IIb unless they:

- are total and partial joint replacements, in which case they are in class III, *with the exception of ancillary components such as screws, wedges, plates and instruments; or*
- **are spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III *with the exception of components such as screws, wedges, plates and instruments.***

2.2 Some considerations to classify spinal implants

1. If only total spinal disc replacements were intended to be up-classified, then there could be no need for exceptions.
2. The term 'ancillary' has not been used but is used for exceptions of TJRs (TJR = Total Joint Replacement). This may to be a conscious decision to only up-classify limited spinal implants.
3. The term 'components' is used in both classification points.
   a. Ancillary components (joint replacement rule) is well understood from 2005/50 (directive of classifying of hip, knee, and shoulder joint reclassification) to mean components that are not always used, but available in a system.
   b. The term 'components' is used for various meanings in the MDR.
      - Article 23 defines a component as something that is defective or worn and can be replaced to maintain or restore the function of the device (parts and components are later referred to as 'items').
      - Article 71 uses the term components for '…usefulness of any components of animal or human origin'.
      - Chapter II; 19.3 states - Active implantable devices and, if appropriate, their component parts…. the devices or their component parts
      - Chapter III; 23.4(k) – IFU: identification of any consumable components and how to replace them (installation - active devices).
      - Annex II, 1, 1.1(j); Device description and specification, …a general description of the key functional elements, e.g. its parts/components
      - Part C (UDI); A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves. (All active devices).
   c. The MDR describes a 'system' as a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose, which introduces a different term to 'components'.
   d. The term 'components' may have been used as a general term that was already used in 2005/50 to simplify all the terms above, whether in a system or not, and which may always be used in the procedure; In article 2 of 2005/50 'component' (component part) is definitely used to describe parts of a larger whole, in this case a TJR.
   e. Definition of component in https://en.oxforddictionaries.com/definition/component: "A part or element of a larger whole, especially a part of a machine or vehicle"

Per this definition, a single product cannot be a component in cases it provides the basic functionality without additional parts; Examples: Cages.

4. The term 'wedge' is not used in spine surgery and thus leaves room for wide interpretation (e.g. a cage may be seen as a wedge)
5. The term 'such as' leaves a wide interpretation of this rule leading to unharmonized addition of devices without ensuring consistency through the different stakeholders, i.e. Notified Bodies and Manufacturers.
6. Spinal disc replacement implants may not just mean total disc replacement – it may also cover other types of implants.

The points above show the complexity of the used wording and its implication on a harmonized implementation of the regulation. Thus, a common understanding document including a decision tree was deemed necessary.

3. Joint NB proposal on a risk-based approach to spinal classification

The following decision tree was created following the legal text of the Medical Device Regulation ensuring a harmonized classification of spinal implants by both manufacturers and notified bodies.

3.1 Commonly Developed NB-Decision Tree on Rule 8 Spinal Classification per MDR

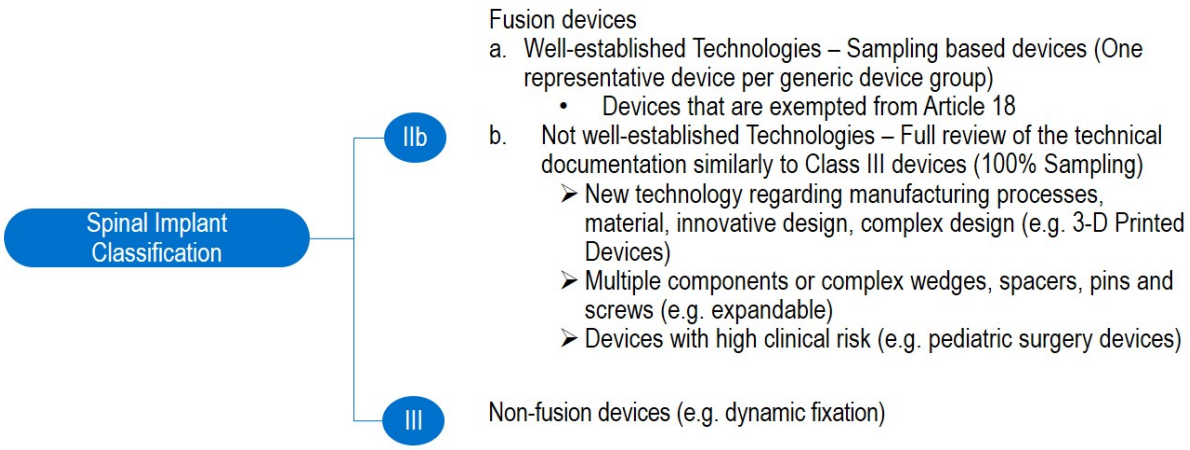

Figure 1: Decision Tree on Spinal Classification

3.2 Interpretation of the Decision Tree on Spinal Implant Classification

The above presented decision tree considers that all spinal disc replacement implants or implantable devices in contact with the spinal column must be classified as class III medical devices. This decision tree is just allowing the correct and harmonized interpretation of the exemption list of the medical device regulation.

Generally, implant technologies utilized in spine surgery can be categorized into two groups:

a. fusion devices (which fuse together two or more vertebrae), and
b. non-fusion devices (which attempt to keep the segmental motion between vertebrae).

At present, fusion devices represent the current state-of-the-art (WET: Well-Established Technology), whereas non-fusion devices are alternative designs (Not-WET: Not Well-Established Technology) which are controversy discussed within the medical society of spine surgeons. To reflect a risk-based approach as described above, a distinction was done between non-fusion devices that must be classified as class III, and the fusion devices that are exempted to stay as class IIb but divided into two categories:

1. Category 1 will be sampled following the typical rules for class IIb devices (at least one representative technical documentation per generic device group)
2. Category 2 will be fully sampled similarly to class III devices (Class IIb Implants process as described in the regulation and not belonging to the exemption list)

These categories were created to address the risk associated with the various implant types and to clearly define the level of scrutiny needed by the notified bodies when overseeing the manufacturer of such devices.

With this decision tree a reduced number of unnecessary submission for clinical evaluation consultation (Article 54) is achieved. This is in line with the focus of the planned expert panel which is novel devices and devices with possible major clinical or health impact. With this measure a smaller number of experts at the panel are needed reducing the burden on the EU Commission to establish such an expert panel within a short period of time.

4. Outlook on future consequences with regards to scrutiny

With this position paper notified bodies are providing their view and interpretation to the various EU regulators including the European Commission enabling them to comment and correct if deemed necessary. This proposal is considering the current state of the art and the risk-based approach defined as the standard methodology for decision making during regulatory approval processes.