

Reclassification

Lessons from a Notified Body

Updated February 2016



1 Background to Upcoming Reclassification

On September 26, 2012 the EU Commission released its proposal for future regulation of medical devices. Within the package, the current three Directives on Active Implantable Medical Devices (AIMD), Medical Devices (MDD) as well as In Vitro Diagnostic Medical Devices (IVDD) are replaced by two Regulations, one covering all Medical Devices, the other covering IVDs. On final agreement the texts will be published in the Online Journal of the EU, the legislation will then gradually come into force with a final transition timeline of three years (MDR) and five years (IVDR) post publication.

As a result of the current proposals all joint replacement devices will be reclassified from Class IIb to Class III. This includes spinal devices, partial hip, knee and shoulder devices and extremity joints such as wrists, ankles and elbows. The scrutiny of the technical documentation (design dossier) these devices will undergo by the Notified Body will increase considerably. It is therefore important for joint implant manufacturers to be prepared and be aware of the implications of this regulatory change on their technical documentation and placing of the product on the market.

2 Lessons Learned from Total Joint Reclassification

In 2005, total hip, knee and shoulder joint replacements were reclassified from Class IIb to III (2005/50/EC), with a transition period between 2007 and September 2009. Products could no longer be placed on the market after the September 1, 2009 deadline if they did not meet the Class III requirements. BSI would like to share their experience from the previous reclassification exercise in order to help you plan for the changes to come.



The impact on your business

What are the risks of not reclassifying your products in time?

- Product withdrawal
- Missed or declining revenue
- Market opportunity is missed
- Market share is missed
- Market expectation is missed
- Plans and forecasts are missed
- Boardroom dissatisfaction

Start preparations
(gap analysis with
MDD class III & new MDR)

Early
submissions
possible

Last chance
for standard
rate review

Final submissions
(@expedited
rates only)

Full
implementation
date

- Start performing Gap assessments.
- Talk with your Notified Body.
- If possible request a Class III review to assess quality of technical documentation.
- Share your plans with your Notified Body.

- Early and standard rate submissions will allow for any gaps to be identified early – and allow enough time for MFRs to address the issues.

- Only expedited rate reviews will be accepted by BSI.
- These may not complete approval in time to meet implementation date.

40-24 months

6-18 months

3 months

3 Differences between requirements for class IIb and class III devices.

- Class III devices undergo an additional design examination and are certified on a Design Examination certificate.
 - All product codes and variants must be identified on the certificate.
 - Any changes or additions to the product codes or variant must be reviewed and approved by the Notified body.
- Increased strength of requirement for Clinical investigation and evaluation.
- Greater expectation of "proactive" post market surveillance, and in particular, post market clinical follow up studies.
- Review for class III devices is not a sampling process, unlike for class II devices which is done a sampling basis.
- Deficiencies must be corrected prior to approval – corrective action plans cannot be accepted.
- Notified Bodies shall notify the Commission and MDCG of new applications for class III devices and estimate for certification date (includes draft IFU & Summary of Safety & Performance).

4 Points to note:

Design Dossiers should be submitted for each family of products, avoiding bundling multiple brands and product families into a single dossier. Include Product Portfolio Strategic Planning, ensuring you consider:

- 1 are all products strategically important in the EU?
- 2 are you planning to remove any products from the market, or consolidating your product portfolio in the near future?
- 3 are the older and/ or low sales volume products adequately supported by design verification, post market surveillance and clinical data? For devices that have been on the market for a number of years clinical data on the device itself will be expected.

5 Start Planning **NOW**, talk with your Notified Body.

Trust your Notified Body

At BSI, we understand that having confidence in your Notified Body is important to an efficient and hassle-free CE marking process. Our approach focuses on open communication from the very beginning. Your product will be supported by a dedicated team of orthopaedic experts interested in sharing the knowledge and passion you have for your products.

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI, please **call or email us for an initial conversation**

Your resource in worldwide compliance: Call BSI today on +39 02 66 79 091 or visit bsigroup.com/it-IT/Dispositivi-Medici – to start your journey



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