



THE MEDICAL DEVICE CONSULTING,
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**PROPOSED NEW EUROPEAN REGULATION
FOR MEDICAL DEVICES TO REPLACE
93/42/EEC AND 90/385/EEC**

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THE INTRODUCTION



The Commission proposal for a new regulation to cover medical devices and active implantable medical devices was published on 26 September

2012. It will eventually replace two directives: 90/385/EEC for Active Implantable Medical Devices (AIMDD) and 93/42/EEC for Medical Devices (MDD).

The proposal is the result of long discussions between the Commission and stakeholders in the 27 Member States and aims to address the perceived weaknesses of the previous regime. Some of these weaknesses were highlighted by the PIP and metal-on-metal issues which led to further discussion and debate. No doubt the current BMJ/Daily Telegraph investigation into consistency between Notified Bodies (NBs) will also have an effect when the proposal is reviewed by the European Parliament and Council during the co-decision process.

If there is agreement at the first reading, the regulation will be published in the Official Journal of the European Union and could take effect by 2015. Full compliance will not become mandatory for three years to allow stakeholders to adopt and implement the new requirements. However, there is also the possibility that the debate will be extended, delaying the implementation date.

At the same time as the proposed MDD/AIMDD replacement regulation, the Commission also published a separate proposal for a new regulation for IVDs to replace Directive 98/79/EC, based on similar principles and considerations. This proposal is expected to follow a similar path toward adoption and implementation, but probably with less discussion and controversy.

Unlike the directives, the regulations will apply directly to Member States without needing to be transposed into local legal systems. This aims to reduce inconsistencies stemming from varying transpositions, but does not address any differences in the way the Member States translate, interpret or implement the regulation.

THE PROPOSAL



The most obvious difference between the draft regulation and the two directives it replaces is that the draft runs to 194 pages, as opposed to 60 for the MDD and 35 for the AIMDD.

Overall, the new regulation follows the principles behind the directives under the New Approach (now re-branded as New Legislative Framework), although the new regulation has much more detail and rigour. For example, it makes compulsory much of the guidance (e.g. concerning vigilance and



clinical data) in Meddevs¹ and GHTF² documents, and includes 50 definitions instead of the original 14.

The new regulation appears to be based on a life-cycle approach to medical

devices, from design through clinical trials to post-market issues. The main changes and features are that the regulation:

- **Extends the definition of “medical device”** to include products without a medical purpose that are similar to medical devices in characteristics and risk profile (e.g. non-corrective contact lenses and implants for aesthetic purposes)
- **Mandates manufacturers to employ a Qualified Person** who possesses expert knowledge in the field of medical devices and has a relevant degree or equivalent plus five years’ professional experience
- **Provides much more detail on the obligations of “economic operators,”** e.g. authorised representatives, importers and distributors
- **Sets up a Medical Device Coordination Group (MDCG)** comprising Member

¹ Meddevs are official guidance documents agreed by Member States and issued by the EU Commission: http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm

² GHTF is the Global Harmonisation Task Force which issued guidance documents agreed by its stakeholders (USA, EU, Australia, Japan and Canada) plus industry and Conformity Assessment Body representatives to foster harmonisation of medical device regulation: <http://www.ghtf.org/documents/>

State representatives to coordinate the regulation’s ongoing implementation and management

- **More closely defines the conduct of clinical investigations,** including the reporting and investigation of adverse incidents and parts of ISO 14155 are included
- **Provides for Member State scrutiny of Class III devices** (via the MDCG) of which NBs will have to notify all applications and provide summary data on request. The practicalities are unclear, although the Commission has said it would scrutinise only 10 percent of such products and that the process would not take more than 90 days.
- **Requires much more information to be made public** via Eudamed, the central EU database for medical devices
- **Makes much greater demands for product traceability** throughout the product lifecycle, including by means of a “Unique Device Identification System”
- **Provides for better coordination of the vigilance system,** including investigation and subsequent action
- **Sets much more detailed and rigorous requirements for Notified Bodies,** especially their competency and expertise. It also requires complete re-evaluation and designation of all NBs which could result in significantly fewer NBs
- **Mandates NBs to carry out unannounced audits** of manufacturers and to take sample products for examination
- **Provides for better coordinated and enhanced market surveillance** by Member States

However, many areas are largely unchanged. For example, although the **conformity assessment routes** are described in much more detail, they are basically similar to the originals.

Classification rules, although basically similar, contain three extra rules making apheresis devices, nano-materials and substances inhaled, ingested or administered rectally or vaginally Class III.

General safety and performance requirements are basically similar to the old essential requirements, but with a GHTF influence. Labelling requirements are much more detailed.

The role of **Harmonised Standards** as a method of showing compliance appears unchanged, although the concept of a common technical specification (CTS) is introduced from the IVD world.

The requirements for **systems and procedure packs** are largely unchanged and there is still provision for **custom-made devices** which remain exempt from many of the requirements.

Own-brand labelling is not mentioned, as was the case with the directives, although this may yet come under scrutiny.

CONCLUSIONS

The proposed regulation is much longer, more detailed and more specific than the current directives and will take a lot of digesting. There may well be significant changes during the co-decision process, but it is unlikely that the basics will be changed much. One possible exception is principles and the practicalities of the proposal for

MDCG scrutiny of high-risk devices which many industry stakeholders oppose but for which there is strong political impetus.



Although the new regulation is much more detailed than the directives it will replace, the basic principles remain the same.

Manufacturers familiar with the current system, including the relevant guidance and harmonised standards, should not find too much difficulty with the new one, with these possible exceptions:

1. **The need for a Qualified Person:** The requirements for this individual are well defined and unlikely to change.
2. **Member state scrutiny of Class III products:** It is not clear how this will work in practice, but it will certainly not reduce the time or cost of bringing these products to market.
3. **Notified Body scrutiny:** This will probably increase from now on as Member States digest the lessons from PIP and metal on metal. This may include unannounced visits and taking of samples for testing as these are already allowed under the current system. Overall, the cost of using a NB is likely to rise significantly.
4. **Post-market traceability:** The unique device identifier is a new concept and it is not known how it will be implemented.

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