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# GUIDANCE DOCUMENT ON DIRECTIVE 2005/50/EC ON THE RECLASSIFICATION OF HIP, KNEE AND SHOULDER JOINT REPLACEMENTS

## 1. Introduction

The purpose of this document is to provide clarification on a number of points to help ensure a common interpretation of Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (the Directive).

It was endorsed by the Commission's Medical Device Expert Group, MDEG, at its meeting of the 12th – 13th December 2006.

The Directive requires that the implantable component parts of total hip, knee and shoulder replacement system to be classified, by derogation to the rules contained in Annex IX of Directive 93/42/EEC, as class III medical devices.

Member States must apply the provisions of the Directive by the 1st September 2007 with a transition period lasting until 1st September 2009, for devices currently approved under Annex II, and until 1st September 2010, for devices currently approved under Annex VI in conjunction with Annex III.

As devices covered by Annex III plus VI are not heavily affected in terms of conformity assessment, this guidance primarily concerns devices currently assessed under Annex II of Directive 93/42/EEC.

## 2. Points of clarification

### 2.1 Scope

Questions have arisen as to the implants that are reclassified. These questions centre around the phraseology in Articles 1 and 2 and in particular the use of the phrase "implantable component part":

*Article 1*

*By way of derogation from the rules set out in Annex IX to Directive 93/42/EEC, hip, knee and shoulder replacements shall be reclassified as medical devices falling within class III.*

*Article 2*

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*For the purpose of this Directive, a hip, knee or shoulder replacement means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint. Ancillary components (screws, wedges, plates and instruments) are excluded from this definition.*

The above construction is deliberate for the following reasons:

Within the preamble to the Directive it is explained that the intention of the legislator, on foot of concerns raised by Member States, is to reclassify hip, knee and shoulder joint replacements, by derogation to the normal rules, into class III.

In particular, in recital (5) and (6) it is identified that the critical replacements that are the focus of concern are those intended to provide a function similar to that of a natural hip, knee or shoulder joint, i.e., replacements which are weight bearing and/or are subject to dynamic forces, replace both articulating surfaces and are connected directly or indirectly to the corresponding bones (i.e., for total hip replacements: femoral components, whether monoblock or modular, and acetabular components).[1]

During discussions at the time of drafting it was understood that these systems were typically placed on the market either as one complete system containing the component parts, or as separate component parts to a system (whereby the surgeon can choose the most suitable combination of different sized and shaped components).

Furthermore, it became evident that within these complete systems, or separately supplied component parts, were ancillary components, such as screws, wedges, plates and instruments etc. It is not the intention of the legislator that such component parts are reclassified into class III, as this would not be proportionate.

Therefore, it was necessary to explain in the text that rather than reclassifying complete systems, it is only those implantable component parts that are intended to function similar to the joint in question that are reclassified, and not screws, wedges, plates, instruments, cutting templates etc.

Further Observations:

1. Total implantable joint replacement systems usually comprise two sets of components: the total joint implant itself – comprised of multiple implanted component parts, including implanted load bearing components and ancillary implanted components (e.g. screws, wedges etc.) and the devices and accessories needed to perform the implant – such as plates, cutting templates and instruments, etc.
2. The objective of Directive 2005/50/EC is to reclassify as class III, implanted load bearing components that function in a similar way to the natural joint.
3. Ancillary implanted components and other supplied devices and accessories are not subject to reclassification and continue to be classified as per the current classification rules[2] (see also point (4)).

[1] EN 12563 – Non-active surgical implants – Joint replacement implants – Specific requirements for hip joint replacement implants (see definitions).

[2] see Annex IX § 2.2. of Directive 93/42/EEC

4. Reclassified component parts are typically placed on the market:
   a) as separate component parts which are indicated to be used as part of a specified total joint replacement, or
   b) as one complete system which contains these component parts.

      Depending on the presentation of this complete system, it may be classified as a whole in class III or subject to the provisions of Article 12 of Directive 93/42/EEC on systems and procedure packs. In any case, it is only the implantable component parts of the system that are classified as class III, and not the various ancillary components mentioned above.

Therefore, for hip, knee and shoulder joint replacements, reclassification into **class III** apply to the **load bearing** components that **function in a similar way to the natural joint**.

These reclassified components are typically placed on the market:

1. As separate component parts, which are indicated to be used as part of a specified total joint replacement.
2. As a complete total joint replacement (including all component parts and accessories of the total joint replacement).
3. As a complete total joint replacement system or procedure pack (including accessories and instruments, etc.).

## 2.2 Transitional arrangements

With respect to the placing on the market and putting into service of devices approved prior to 1 September 2007, the Directive, under Article 3, paragraphs 3 and 4, makes a distinction in the adequate transitional arrangements between those hip, knee and shoulder replacements that were subject to an Annex II conformity assessment and those that were subject to an Annex III plus VI.

Basically, for devices approved under Annex II prior to 1st September 2007, they cannot be placed on the market or put into service after 1st September 2009; whereas for devices approved under Annex III plus VI prior to 1 September 2007, they cannot be placed on the market after 1st September 2010 but they can continue to be put into service after that date

This motivation for this distinction is stated in recital 11, citing the need, in the interests of high level of protection of health, for explicit detailed examination of design prior to introduction in general clinical use.

> *(11) In order to achieve the optimal level of safety and health protection and to reduce the design related problems to the lowest level, the design dossier of hip, knee and shoulder replacements, including the clinical data used by the manufacturer to support the claimed performance and the subsequent post-marketing design and manufacturing changes should be examined in detail by the notified body before these devices are introduced in general clinical use.*

For devices approved under Annex II prior to 1st September 2007, no such detailed examination is required and thus after 1st September 2009 they should no longer be placed on the market nor put into service.

However, for devices approved under to Annex III plus VI prior to 1st September 2007, a detailed examination takes place, so the transition period is longer (until 2010) and after this date they should no longer be placed on the market, but they can be still put into service.

Directive 93/42/EEC defines putting into service as:

> *"(i) 'putting into service' means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;"*

As the final user in this case is the medical professional, the stage at which the device is put into service is when it is available for general clinical use by the surgeon, either by his purchase, or purchase on the surgeon's behalf by a hospital.

Therefore replacements referred to in Article 3 paragraphs 3 and 4 approved prior to 1st September 2007 can be placed on the market until the 1st September 2009 and 1st September 2010 respectively. And within these two categories of devices, those approved under Annex II cannot be put into service (sold to surgeons and hospitals for subsequent implantation) after 1st September 2009, whereas those approved under Annex III plus VI and put on the market before 1st September 2010, can continue to be put into service after that date.

Hip, knee and shoulder replacements that were subject to an **Annex II** conformity assessment prior to 1st September 2007 **cannot** be placed on the market **or** put into service after 1st September 2009 without additional conformity assessment.

Hip, knee and shoulder replacements that were subject to an **Annex III plus VI** conformity assessment prior to 1st September 2007 **cannot** be placed on the market after 1st September 2010 without additional conformity assessment, **but can** be put into service after that date.

For hip, knee and shoulder replacements, **'putting into service'** can be considered to take place when they are **made available to the medical professional**.

## 2.3 Transitional arrangements for products covered by Article 3(1) – Devices approved under Annex II before 1st September 2007.

### 2.3.1 Issue of EC design-examination assessment after 1st September 2009.

Hip, knee and shoulder replacements that have followed an Annex II conformity assessment procedure before 1st September 2009, must undergo a complementary design dossier examination (point 4 of Annex II) to be placed on the market and put into service after 1st September 2009.

This raises the question as to what interpretation can be taken for devices that are still in the assessment process but have not yet received a complementary certificate prior to 1st September 2009.

Here, the interpretation is the same as that for all cases where a manufacturer is aware that his device no longer meets the requirements of the Directives, i.e. a device that does not meet the requirements of the Directive should no longer be placed on the market and put into service until it is brought back in compliance (e.g. suspend shipments, quarantine stocks if necessary, etc. until the EC design-examination certificate is issued)

It should be noted that Notified Bodies that have begun a design dossier examination prior to 1st September 2009 may continue the evaluation. Once the EC design-examination certificate is issued, the placing on the market and putting into service, which were suspended, can be resumed.

Where the examination of a design dossier will pass the 1st September 2009 date, a manufacturer must **suspend** the placing on the market and putting into service of his devices **until** an EC design-examination certificate is issued.

### 2.3.2 Issue of EC design-examination assessment reports prior to 1st September 2007

The Directive entered into force on 1 September 2005. Member States are required to transpose the Directive into national law by the 1st March 2007 and apply its provisions from 1st September 2007.

In the interests of expediency it has been asked if notified bodies could begin their work on design dossier review under Annex II prior to any of these dates.

The Directive, in Article 3 (1) states that:

> *"Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure […] shall be subject to a complementary conformity assessment under point 4 of Annex II […] before 1 September 2009."*

Therefore, provided that the notified body meets the requirements for competence under the Directive, there is nothing preventing applications and examination of the design dossier beginning any date before the 1 September 2009. However, the Directive, in Article 4, requires Member States to apply the Directive from 1 September 2007. Therefore an EC-design-examination certificate may only be issued after that date. In such cases, in lieu of a certificate, the notified body may issue the manufacturer with a draft report of the review.

The notified body and the manufacturer should agree arrangements so that any design changes, as referred to in Annex II paragraph 4.4 of Directive 93/42/EEC, that occur between the date of the draft assessment report and the date the EC-design-examination certificate is expected to be issued, are transmitted to the notified body during this interim period. The Notified Body shall evaluate these design changes to complete the initial report before issuing the final EC-design-examination certificate.

Notified bodies can begin their **examination at any time**; however, an EC design-examination certificate can only be issued after 1st September 2007

As the design change notification requirement under Annex II paragraph 4.4 is only in effect once a certificate is issued, notified bodies and manufacturers should agree arrangements regarding notification and examination of **design changes** prior to the issuing of the certificate.

### 2.4 Examination procedures completed before 1st September 2009 for devices approved under Annex II prior to 1st September 2007

Until the 1st September 2009 cut-off date is reached, hip, knee and shoulder replacements approved under Annex II prior to 1st September 2007, can be placed on the market and put into service as class IIb devices.

However, where between 1st September 2007 and 1st September 2009 a manufacturer applies for an EC certificate, the hip, knee and shoulder replacements in question are class III medical devices and shall be subject to the corresponding evaluation procedures, in particular with respect to change management, periodic audits, etc.

Between 1st September 2007 and 1st September 2009, once a manufacturer of a device approved prior to 1st September 2007 under Annex II, applies for an EC certificate, his device is **class III** and shall be subject to the corresponding evaluation procedures, even if the 1st September 2009 cut-off date has not been reached.