	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	NBM/001/ 07 **Recommendation** **NB-MED/2.5.5/Rec2**

Title:	**Conformity assessment procedures for hip, knee and shoulder total joint replacements**
Chapter:	**2.5.5** Conformity assessment procedures; **Particular product groups**

Text:	**"Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to Article 11(3)(a) of Directive 93/42/EEC before 1 September 2007 shall be subject to a complementary conformity assessment under point 4 of Annex II to Dircetive 93/42/EEC leading to an EC design examination cerificate before 1 September 2009." (Directive 2005/50/EC Article 3(1))**
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1. INTRODUCTION

NBRG 307/07

It is the primary purpose of this document to provide guidance to Manufacturers and Notified Bodies in dealing with the application of Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements adopted by the European Commission on 11 August 2005, hereafter referred to as the Directive[3] and taking into account the MEDDEV……

This guidance is intended to provide clarification on approaches to be taken with hip, knee and shoulder joint replacements already assessed as class IIb medical devices under the full quality assurance system of Annex II point 3 to Directive 93/42/EEC, allowing for their complementary assessment under point 4 of Annex II to the Directive[4]. These products are at various stages in their life cycle from recently developed designs to long-standing products with extensive histories of clinical performance.

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2. SCOPE

This guidance applies to all activities associated with the review of hip, knee and shoulder joint replacements covered by Article 3 (1) of Directive 2005/50/EC for which a complementary conformity assessment is required. This is intended to be applied to a hip, knee or shoulder replacement, which according to the Directive means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of a natural hip joint, a natural knee joint or a natural shoulder joint[5].

Other Class IIb, hip, knee and shoulder joint replacements which have been the subject of a certification following the procedure relating to the EC type examination set out in Annex III to Directive 93/42/EEC, coupled with Annex VI are affected by the Directive but no specific guidance is necessary[6].

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3. APPLICATION OF THE DIRECTIVE TO DEVICES REFERRED TO IN ARTICLE 3 (1)

Directive 2005/50 calls for ~~of~~ a complementary assessment procedure pursuant to point 4 of Annex II to Directive 93/42/EEC if the manufacturer intends to continue to place hip, knee and shoulder total joint replacement implants on the market and put them into service after 1 September 2009.

Manufacturers should submit to NBs a design dossier for every hip, knee or shoulder joint replacement, or family of hip, knee or shoulder joint replacements, which are to be covered by the certification issued under Annex II section 3.1 (ref : Annex II.4).

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The dossier should contain the information necessary for the NB to verify that the relevant and applicable requirements have been met. It should:

- Describe the devices and their intended use and define the range of any variants (e.g. sizes, lengths etc). Where the manufacturer has grouped similar devices into one dossier (a family) the rationale for the grouping (similarities of design, technology, functionality etc) shall be described.

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- **NOTE:** ~~***[NOTE: we suggest to ensure that the definition of category / family be aligned with other published guidance]***~~

A product family is defined as one or more product types that have the following common characteristics:

- *The technical concept is almost identical*
- *The intended use is almost identical*
- *The manufacturing process is almost identical*
- *The classification is identical*
- *The evidence to support compliance to the essential requirements is almost identical and can only differ on minor points from type to type.*
- *The risk analysis of the most complex (worst case) type covers also the risks of the other types in the family*

- Verify the applicability of the complementary conformity assessment process to the devices included e.g. previous Declarations of Conformity/certification.

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MEDDEV 2.10[7] states that, under Annex II para 4, NBs must confirm that the product / family conforms to the relevant provisions of Directive (ERs) by verifying:

- the conclusions of risk analysis
- that all applicable ERs are addressed
- that relevant standards have been applied or other solutions adopted to meet ERs
- the conclusions drawn by the manufacturer concerning the clinical data.

The NB may require further tests or other data to enable this.

Satisfactory assessment will lead to the NB issuing a Design Examination Certificate for each submission (product/family).

~~Manufacturers will suspend placing on the market and putting into service any devices for which a DE certificate has not been issued after 01 September 2009.) [NOTE: we recommend deletion of this sentence as it is already in the Directive]~~

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The amount and detail of the data contained in the design dossier ~~[NOTE: previous wording replaced]~~ will vary according to the device and the age of the design.

Note: ~~A~~an analogous situation is addressed by NBMED/2.13/Rec1[8] for products placed on the market prior to the implementation of 93/42. It says that the manufacturer must assess the available documentation and data and decide if the device and manufacturing process meet the requirements of the directive.

Where the documentation generated at the time of the original/actual design of the product or product family ~~category~~ is insufficient (taking account of the generally acknowledged state of the art) to demonstrate compliance for each family, the above NBMED suggests consideration of the use of clinical evaluation and post-production experience to fill the gap [Ref.: MEDDEV 2.12.2 & MEDDEV. 2.7.1][9, 10].

~~The following two examples illustrate this point:~~

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~~**[NOTE: These examples illustrate NBMEDEV 2.13 situations not the actual approach of a complementary evaluation. It is our understanding that each family of devices covered by a class IIb decision is deemed to satisfy all relevant ERs, but that not every family design dossier has been approved by a Notified Body (cf. MEDDEV 2.12.2 Attachment 3)]**~~

The manufacturer can use post market data to verify some aspects of the safety and performance of a device, eg wear rates and durability.

However, in some cases (eg for sterility or biological safety) post market data may not be sufficient.

Where appropriately verifiable data has been established this can be used in support of a justification for not performing tests suggested by current standards.

- ~~The originally generated design dossier may not contain any sterilisation validation. In this case, it is not possible to deduce from post-market data that a sterilisation cycle is satisfactory and so compliance with ER8.3 must be based on appropriate verifications and validations.~~
- ~~The original wear testing on a hip joint replacement did not meet the current ISO 14242-1:2002 requirements, nor was it equivalent in rigour. In this case, it may be possible to use experience post-market as evidence of durability.~~

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~~•The original data did not fully determine the compatibility of the implant with other associated devices e.g. surgical instruments. For a new or novel design the manufacturer may need to consider performing clinical investigation or simulated use testing to verify the combination, or it may be possible to use experience post-market for this ER.~~

~~Risks related to biological safety would not be considered to be able to be fully addressed by post market experience. But where appropriately verifiable data has been established this can be used to support other data e.g. materials characterisation, published data on use of the materials in similar clinical situations etc. in support of a justified waiver for not performing tests indicated by the relevant standards.~~

In general, the longer a product has been on the market, the more likely it is that the post market surveillance data can be used to supplement pre-market design verification data in order to give confidence in meeting relevant ERs.

When examining the clinical post market implant data, the requirements of MEDDEV 2.7.1 and MEDDEV 2.12.2 should be borne in mind. In particular:

- The data must be relevant to the device / family currently being placed on the market; changes to the product which have been made since it was first marketed should be

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documented and evaluated to determine the degree of ~~equivalence~~ similarity of the various versions of the product

- The data should be evaluated to determine how many products have been truly followed up and how many are lost to follow-up; a lack of reported incidents may not necessarily be because there have been no problems

Data common to several implants or implant families, for example on the validation and control of key processes such as sterilization, packaging and cleaning, may be submitted to the Notified Body in the form of "Master Files".

4. TRANSITIONAL ISSUES

The following guidance pertains to specific transitional issues related to the application of the Directive.

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4.1 Commencement of Application of Directive:

A Notified Body may, at the manufacturer's request, start the evaluations requested by the Directive after its entry into force and may issue a n examination report before 1 September 2007. However, the EC-design Examination Certificate shall only be issued after 1 September 2007. The certificate will be valid for a maximum period of 5 years to be agreed by both parties.

4.2 Transitional Period

The complementary conformity assessment evaluation by a Notified Body of a HKS replacement Design Dossier submitted before 1 September 2009, is allowed to may continue after 1 September 2009 with the intent of issuing an EC-design Examination Certificate.

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~~However from 1 September 2009, the manufacturer will suspend the placing on the market of affected products until an EC design Examination Certificate is issued.~~

4.3 Time Frames for Design Dossier Submission and Notified Body Review

As ~~T~~the change in classification of joint replacements will introduce an additional burden for all parties, ~~on the Notified Body review process. It~~ it is ~~therefore~~ prudent for manufacturers and Notified Bodies to establish ~~acceptable~~ timeframes for the submission~~review and approval~~, review and approval of design dossier files. ~~submitted to Notified Bodies for existing products under the Directive. Each m~~Manufacturers are ~~is~~ encouraged to contact their Notified Bodies ~~y~~ to plan the submission strategy and agree ~~to~~ appropriate ~~review~~ timelines.

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5. REFERENCES:

1. Commission Directive 2005/50 of August 11 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices
2. Commission Directive 2005/50 of August 11 2005 – Article 3 paragraph 1.
3. Commission Directive 2005/50 of August 11 2005 – Recital point 2.
4. Commission Directive 2005/50 of August 11 2005 – Recital point 14.
5. Commission Directive 2005/50 of August 11 2005 – Article 2
6. MEDDEV 2.5-2 - Quality Assurance. Regulatory Auditing of Quality Systems of Medical Device Manufacturers (see also GHTF Document)
7. MEDDEV 2.10-2 Rev. 1 April 2001 – Designation & Monitoring of NBs within the Framework of the EC Directives on Medical Devices
8. NBMED/2.13/Rec1 1.08.98 – Commission Communication on the Application of Transitional Provisions of Directive 93/42
9. MEDDEV 2.12.2 – May 2004 – Guidelines on Post market Clinical Follow-Up

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10. MEDDEV. 2.7.1 April 2003 – Guidelines on Medical Devices – Evaluation of Clinical Data: A Guide for manufacturers and Notified Bodies