PROPOSAL FOR NEW WORK ITEM

PROTECTING PUBLIC HEALTH TOGETHER

PART A: TO BE FILLED IN BY THE APPLICANT

Title Proposed work item (Max 5 keywords)

Content of declaration of conformity

CMC-Board History (list of references of all relevant communication to/from CMC-Board concerning this work item)

None. (first application to CMC Board)

Applicant

- **Applicant member of CMC**

☐ AT ☐ BE ☐ BG ☐ CH ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE

☐ ES ☐ FI ☐ FR ☐ GR ☐ HR ☐ HU ☐ IE ☐ IS ☐ IT

☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☒ PL ☐ PT

☐ RO ☐ SE ☐ SI ☐ SK ☐ TR ☐ UK

- **Applicant not within CMC-members**

☐ Working Group Name WG:

☐ Other: Name Organisation:

Address:

Contact person:

Telephone No: Fax No:

E-mail:

Date:

Proposed work item

Decision on content of declaration of conformity issued by manufacturers of medical devices by Central Management Committee and agreement of necessary data which have to be given in declaration of conformity.

Rationale for application

Declaration of conformity issued by manufacturer of medical devices is the most important document apart from the certificate (if applicable). It is the proof that a conformity assessment procedure by manufacturer has been performed and it is often used as basic document during market surveillance and customs procedures.
Due to the fact that the content of such a document is not precisely stipulated in the legislation, it is sometimes difficult to identify if a particular device is the subject of declaration of conformity and sometimes it is difficult to link the content of the declaration of conformity to a NB certificate.

Arguments pro and against NWI
Supporting information (Working Groups, CAMD, etc.)
Is there a consensus among Member States?
What are the main reasons of lack of consensus?

2007/47/EC Directive of European Parliament and of the Council of 5 September 2007 has changed two directives 90/385/EEC and 93/42/EEC. New provisions are marked as M4 (90/385/EEC) and M5 (93/42/EEC) amendments in consolidated text. Among those amendments there are new provisions for written declaration of conformity, e.g.. Annex 2 of 90/385/EEC point 2 second sentence “Declaration shall cover one or more clearly identified devices by means of product name, product code or other unambiguous reference”. While working on new regulations and during many meetings Competent Authorities representatives have expressed a need to define a set of data which shall be drawn up in declaration.

Action/Decision proposed by applicant

COEN shall develop a scheme that defines a set of data which shall be included in the declaration of conformity. Based on that scheme the CMC shall decide that CA’s will enforce the harmonised application of the scheme.

Proposal for the lead official:

PL: Joanna Kilkowska

Supporting information (Working Groups, CAMD, etc.)
+ History of discussion: provide here the list of hyperlinks to relevant documents (eg. CIRCA)

See additional information:

1. MDEG -2009-12-01 MSOG Class I Guidance (Compliance and Enforcement Group) ClassIGuidance_Rev1.doc ; chapter “Step 4 – Draw-up the EC Declaration of Conformity” where such description could be found : **“**The declaration of conformity should contain all information to identify the Directives to which it is issued, as well as the manufacturer, the authorised representative, the Notified Body and the product, and where appropriate a reference to harmonised standards or other relevant

documents."

- http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/notes-for-manufacturers-class1-09_en.pdf

2. EN ISO /IEC 17050-1:2010 Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements (ISO/IEC 17050-1:2004) – this is the harmonised standard published in Official EU Journal of law 2009/C 136/08;

3. Guide to the implementation of directive based on the New Approach and the Global Approach; chapter 5.4 "EC declaration of conformity" (page 34-35) where minimum information required in declaration are described.

- http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

PART B: TO BE FILLED IN BY THE CMC-BOARD

Proposed work item	Within scope of CMC?	☒ Yes	☐ No
	Is Proposal mature for CMC ?	☒ Yes	☐ No
	Recommendations:		
	Give COEN the task to develop the scheme		
Rationale for application	Description complete?	☒ Yes	☐ No
	Recommendations:		
Arguments pro and against NWI Supporting information (Working Groups, CAMD, etc.) Is there a consensus among MS? What are the main reasons of lack of consensus?	Description complete?	☒ Yes	☐ No
	Recommendations:		
Proposal for the lead official	Accepted?	☒ Yes	☐ No
	Proposed alternative candidate:		
Supporting information (Working Groups, CAMD, etc.) + History: provide here the list of links to relevant documents (eg. CIRCA)	Documentation complete?	☒ Yes	☐ No
	Recommendations:		

PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	**23.02.2011**
CMC meeting agenda item	**8.d. NWIP – Content of the Declaration of Conformity-**
Transfer to CMC meeting	☒ For consideration ☒ For appointment of the lead official ☒ For allocation of work ☐ For decision
Action/Decision proposed Accept the NWIP	
Proposal for the lead official: PL Joanna Kilkowska	
Proposal for the allocation of potentially necessary additional preparatory work: COEN	
Proposed work planning and timing to output: Finalisation of the NWIP until the CMC – December meeting 2011	
Conclusion of the CMC-Board: CMC should consider the acceptance of the NWIP Date: 25.01.2011	

REFERENCE N° CMC-Board**:**