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 Notified Bodies Certificates

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

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

Development of mandatory requirements for certificates issued by Notified Bodies according to the various Annexes of the MDD, IVDD and AIMDD.

Rationale for application

The existing medical device directives do not clearly specify the content of certificates to be issued by Notified Bodies. In addition, Notified Bodies currently have partly different understanding of the required content (e.g. titles, references to the directives, the degree of details concerning the devices or device groups covered by the certificate, addresses of manufacturers, and information on the validity of certificates). These differences impede or make it very difficult for CAs to verify the status of certificates and are partly not understandable for persons, which are not so familiar with the medical device regulations like distributors, health care institutions or users.

Clearly defined requirements regarding the content of certificates should enhance the actor's understanding of certificates.

NBOG BPG 2010-3 has been established to specify a minimal content of the certificates, but some Member States expect much more detailed information.

Arguments pro and against NWI

The discussion about the content of the certificates increased (in WGs and with the market surveillance staff in Member States) since the publication of the document NBOG 2010-3. Today the interpretations and expectations of Member States with regard to certificates are considerably different. Several discussions in NBOG showed differences in the expectation of certificate contents. Some Member States expect a detailed listing of all devices (including their classification and intended use) covered by a certificate. Others argue – in line with the red tape initiative – for a two-layer system with a summarized description of medical device groups or families on quality system certificates (e.g. MDD Annex II (exempt 4), Annex V or VI) and a traceable list maintained by the manufacturer and the Notified Body containing details of individual devices/articles being covered by the certificate.

The current directives do not clearly specify requirements for Notified Body certificates. NBOG BPG 2010-3 defines more specific requirements than the directives.

Action/Decision proposed by applicant

1. Reach consensus among the MS:

   Since the minimal content of the certificates is an ongoing discussion, in a first step the purpose of the certificates needs to be defined. This is a necessary set up for defining the minimum content requirements **under existing legislation as well as for the future legislation**.

   In that context it needs to be clarified who is using the certificates for what. E.g. how does a CA handle the document in market surveillance cases (to define further market surveillance steps, evidence to take measures against economic operators etc.).

   In addition the consequences of detailed information requirements for manufacturers, Notified Bodies, CAs (validity of certificates, data integrity in EUDAMED), and users of certificates (e.g. distributors, health care organisations, users) should be considered.

   All this information is essential to move forward in achieving a consensus or acceptance in at least a vast majority of member states. The already agreed questionnaire to be set up by NBOG should

be verified and used for gathering relevant information.

2. With respect to the existing legislation, revise NBOG BPG 2010-3 and commit to the implementation of this guide and
3. Define the minimum content of certificates to be implemented in the revised directives or to be made mandatory via the regulatory procedure referred to in Article 7(2) MDD.

Proposal for the lead official:

CH Peter Studer

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

- current best practice guide 'NBOG_BPG_2010_3'
- previous version of this document 'NBOG BPG 2006-2'

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:		
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:		

REFERENCE N° CMC-Board**:**

PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	23.02.2011
CMC meeting agenda item	**8c NWIP -** Clarify the content of Notified Body certificates
Transfer to CMC meeting	☒ For consideration ☒ For appointment of the lead official ☒ For allocation of work ☐ For decision
Action/Decision proposed Start elaboration of a detailed proposal on the Content of Notified Bodies certificates	
Proposal for the lead official: CH Peter Studer	
Proposal for the allocation of potentially necessary additional preparatory work: NBOG	
Proposed work planning and timing to output: finalisation until autumn of 2011	
Conclusion of the CMC-Board CMC should accept the NWIP Date: 25.01.2011	