PROTECTING PUBLIC HEALTH TOGETHER

CMC WORK ITEM

PART A: TO BE FILLED IN BY THE APPLICANT

Title Proposed work item (Max 5 keywords)

Revised designation process for notified bodies

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:

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Proposed work item
To review the existing process for designation and ongoing review of the scopes of designation of notified bodies for medical devices by Member States to provide a mechanism where these designation decisions are taken following involvement of other Member State experts into the review. The mechanism should also allow for coordinated advice on proposed or existing designations to be provided based on the outcome of the independent reviews by the designating Member State and other Member State experts. The new designation procedure should ensure a harmonised high level of performance of Notified Bodies.
This work item may include revisions to Article 16 of 93/42/EEC and corresponding text in other Directives and possibly the addition of an Annex to detail the procedure.

Rationale for application
Harmonisation of the performance of notified bodies for medical devices and careful review of existing designated scopes to ensure they are appropriately aligned with available competencies is crucial to the effectiveness of the regulatory system and to increase trust in that system.

Establishing harmonised criteria for designation of notified bodies is one necessary activity but it is also necessary to ensure that authorities are applying criteria and standards evenly, are conducting appropriate reviews and are taking appropriate designation decisions. To ensure a high and harmonised quality of such decisions it seems to be necessary that the assessment by the Member State Authority has to be supported by an independent assessment made by other MS expert/expert team. Such enhanced cooperation and coordination of designation decision making would help to achieve this.

Having a collaborative approach to designation review prior to Member State decision would allow for a second opinion confirming the designation scope.

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?

There is generally agreed recognition among Member States on the need to improve performance of notified bodies, harmonise their monitoring and designation and this proposed work item is a critical step in that process.
This topic has previously been discussed and in principle supported by the Competent Authority for Medical Devices meeting in (Uppsala, the Medical Device Expert Group Meeting (closed session) and by the Notified Body Operations Group meeting.

Member states have legal autonomy to designate certification bodies as notified bodies for medical devices. Member states may be concerned that cooperating and receiving advice/input from other Member State colleagues on designation decisions may be reducing this autonomy, however the motive is to improve the effectiveness of the system. This should be duly considered during the development of a revised process for designation and monitoring of NB.

Action/Decision proposed by applicant

Small group to be established by the Notified Body Operation Group and by the Central Management Committee to scope, review and make a proposal for a mechanism to enhance coordination and decision making of the designation of notified bodies and amendment of Article 16 and associated texts as

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appropriate
Proposal for the lead official: IR Niall MacAleenan
Supporting information (Working Groups, CAMD, etc.) + History of discussion: provide here the list of hyperlinks to relevant documents (eg. CIRCA) • **Designating authority handbook** • **NBOG Report for the Period 2005 - 2008** • **Prague resolution on recast of the medical devices directives, 23rd Competent Authority Meeting for Medical Devices.** • **Development of the regulatory system - Assessment of notified bodies, 24thCompetent Authority Meeting for Medical Devices NBOG-35-09** • **Development of the regulatory system - Notified Bodies in the Recast 25th Competent Authority Meeting**

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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:		

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PART C: RECOMMENDATION FROM CMC-BOARD TO CMC

CMC meeting date	**23.02.2011**
CMC meeting agenda item	8 b Design a new designation procedure for Notified Bodies
Transfer to CMC meeting	☒ For consideration ☒ For appointment of the lead official ☒ For allocation of work ☐ For decision
Action/Decision proposed Acceptance of the NWIP, Start of the preparatory work	
Proposal for the lead official: **IR Niall MacAleenan**	
Proposal for the allocation of potentially necessary additional preparatory work: Small group to be established with experts from NBOG and CMC	
Proposed work planning and timing to output: First draft until Summer 2011	
Conclusion of the CMC-Board CMC should consider the acceptance of the NWIP Date: 07.06.2011	