

## **MDCG 2019-12**

### **Designating authority's final assessment form: Key Information (EN)**

**October 2019**

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Designating authority's final assessment form: Key Information (EN)

<b>Date</b>			
<b>Country of the designating authority and name (optional)</b>			
<b>Name of the conformity assessment body (CAB) / notified body (NB) and identification number (if applicable)</b>			
<b>Date of on-site assessment</b>		<b>Purpose of the assessment</b>	<b>Tick</b>
		Initial designation	<input type="checkbox"/>
<b>Date of follow up on-site assessment (if applicable)</b>		Renewal of designation	<input type="checkbox"/>
		Scope extension	<input type="checkbox"/>
<b>Regulation</b>			<b>Tick</b>
Regulation (EU) 745/2017			<input type="checkbox"/>
Regulation (EU) 746/2017			<input type="checkbox"/>

<b>Summary of the designating authority assessment</b>		
<b>Brief description of the assessment carried out by the designating authority</b>		
<i>Please provide a summary of the result of the assessment carried out by the designating authority</i>		
<b>Have all corrective and preventive actions been appropriately addressed and, where required, implemented?</b>	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
<i>Provide a justification if the answer is NO</i>		

<b>Remaining diverging opinions</b>		
<b>Is there any remaining diverging opinion with the JAT?</b>	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
<b>1</b>	<i>If applicable, please provide information on any remaining diverging opinions with the JAT including<sup>1</sup>:</i> - designating authority's opinions raised on-site, <u>and</u> - any updates to these opinions	
<b>2</b>	<i>See above</i>	

<sup>1</sup> A new row with the information indicated in this section should be repeated for each diverging opinion.

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Designating authority recommendation for designation (Tick as applicable)	
<input type="checkbox"/> Designation of the CAB / NB <b>not</b> recommended <input type="checkbox"/> Designation of the CAB / NB recommended <input type="checkbox"/> Designation of the CAB / NB recommended with the following condition(s):	
1	<i>Provide information on any conditions to be established as part of the designation<sup>1</sup></i>
2	<i>See above</i>

Designating authority recommended scope of designation (Tick as, and if, applicable)	
See appended form <insert file name> (based on "NBOG F 2017-3")	<input type="checkbox"/>
See appended form <insert file name> (based on "NBOG F 2017-4")	<input type="checkbox"/>
<input type="checkbox"/> Scope of designation proposed by designating authority is the <b>same</b> as that applied for by the CAB / NB <input type="checkbox"/> Scope of designation proposed by designating authority is <b>different</b> to that applied for by the CAB / NB	
<i>In case the scope of designation proposed differs in respect to the applied for scope please provide an explanation:</i>	

List of non-conformities and designating authority's assessment of the corrections and CAPAs proposed by the CAB / NB			
No	Non-conformity	CAPAs proposed by CAB / NB	Assessment by the designating authority
<b>Organisational and general requirements</b>			
1.	<i>Description on the non-conformity</i>	<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Non-conformity</b>
			<input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			<b>Implementation of CAPA</b>
		<b>Additional description of CAPA<sup>2</sup>/remarks:</b>	<b>Effectiveness of CAPA</b>
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation

<sup>1</sup> A new row with the information indicated in this section should be repeated for each condition on designation.

<sup>2</sup> Where possible, this section should describe in brief terms what specific elements have been addressed by the corrective and preventive action (CAPA) with regard to the items ticked above. For example, when actions include a change or revision of procedures, the description should indicate the nature of the change.

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2.		<p><b>Type of CAPAs - Tick as many as applicable</b></p> <p><input type="checkbox"/> Change of procedure(s)</p> <p><input type="checkbox"/> Revision of existing procedures</p> <p><input type="checkbox"/> Creation of new/additional QMS document(s)</p> <p><input type="checkbox"/> Training of personnel</p> <p><input type="checkbox"/> Rework of personnel file(s)</p> <p><input type="checkbox"/> Rework of project file(s)</p> <p><input type="checkbox"/> Contract with new internal / external personnel</p> <p><input type="checkbox"/> CAPA insufficient / missing</p>	<p><b>Non-conformity</b></p> <p><input type="checkbox"/> Closed</p> <p><input type="checkbox"/> To be followed-up</p> <p><b>Implementation of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
		<p><b>Additional description of CAPA/remarks:</b></p>	<p><b>Effectiveness of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
3.		<p><b>Type of CAPAs - Tick as many as applicable</b></p> <p><input type="checkbox"/> Change of procedure(s)</p> <p><input type="checkbox"/> Revision of existing procedures</p> <p><input type="checkbox"/> Creation of new/additional QMS document(s)</p> <p><input type="checkbox"/> Training of personnel</p> <p><input type="checkbox"/> Rework of personnel file(s)</p> <p><input type="checkbox"/> Rework of project file(s)</p> <p><input type="checkbox"/> Contract with new internal / external personnel</p> <p><input type="checkbox"/> CAPA insufficient / missing</p>	<p><b>Non-conformity</b></p> <p><input type="checkbox"/> Closed</p> <p><input type="checkbox"/> To be followed-up</p> <p><b>Implementation of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
		<p><b>Additional description of CAPA/remarks::</b></p>	<p><b>Effectiveness of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
<b>Quality management system requirements</b>			
4.		<p><b>Type of CAPAs - Tick as many as applicable</b></p> <p><input type="checkbox"/> Change of procedure(s)</p> <p><input type="checkbox"/> Revision of existing procedures</p> <p><input type="checkbox"/> Creation of new/additional QMS document(s)</p> <p><input type="checkbox"/> Training of personnel</p> <p><input type="checkbox"/> Rework of personnel file(s)</p> <p><input type="checkbox"/> Rework of project file(s)</p> <p><input type="checkbox"/> Contract with new internal / external personnel</p> <p><input type="checkbox"/> CAPA insufficient / missing</p>	<p><b>Non-conformity</b></p> <p><input type="checkbox"/> Closed</p> <p><input type="checkbox"/> To be followed-up</p> <p><b>Implementation of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
		<p><b>Additional description of CAPA/remarks::</b></p>	<p><b>Effectiveness of CAPA</b></p> <p><input type="checkbox"/> Already verified</p> <p><input type="checkbox"/> To be verified following designation</p>
5.		<p><b>Type of CAPAs - Tick as many as applicable</b></p> <p><input type="checkbox"/> Change of procedure(s)</p> <p><input type="checkbox"/> Revision of existing procedures</p>	<p><b>Non-conformity</b></p> <p><input type="checkbox"/> Closed</p> <p><input type="checkbox"/> To be followed-up</p>

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		<input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Implementation of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		<b>Additional description of CAPA/remarks::</b>	<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
<b>Resource requirements</b>			
6.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		<b>Additional description of CAPA/remarks::</b>	<b>Implementation of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		<b>Additional description of CAPA/remarks::</b>	<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
7.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		<b>Additional description of CAPA/remarks::</b>	<b>Implementation of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		<b>Additional description of CAPA/remarks::</b>	<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
8.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s)	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			<b>Implementation of CAPA</b>

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		<input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		<b>Additional description of CAPA/remarks::</b>	<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
<b>Process requirements</b>			
9.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		<b>Additional description of CAPA/remarks::</b>	<b>Implementation of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
			<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
10.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel <input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		<b>Additional description of CAPA/remarks::</b>	<b>Implementation of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
			<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
11.		<b>Type of CAPAs - Tick as many as applicable</b> <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s) <input type="checkbox"/> Training of personnel	<b>Non-conformity</b> <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			<b>Implementation of CAPA</b>

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		<input type="checkbox"/> Rework of personnel file(s) <input type="checkbox"/> Rework of project file(s) <input type="checkbox"/> Contract with new internal / external personnel <input type="checkbox"/> CAPA insufficient / missing	<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		<b>Additional description of CAPA/remarks::</b>  	<b>Effectiveness of CAPA</b> <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation