

MDCG 2019-12

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

October 2019

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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

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

Remaining diverging opinions		
Is there any remaining diverging opinion with the JAT?		Yes <input type="checkbox"/>
		No <input type="checkbox"/>
1	<i>If applicable, please provide information on any remaining diverging opinions with the JAT including¹:</i> - designating authority's opinions raised on-site, <u>and</u> - any updates to these opinions	
2	See above	

Designating authority recommendation for designation (Tick as applicable)	
<input type="checkbox"/> Designation of the CAB / NB not 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	Provide information on any conditions to be established as part of the designation ²
2	See above

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 same as that applied for by the CAB / NB <input type="checkbox"/> Scope of designation proposed by designating authority is different 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
Organisational and general requirements			
1.	<i>Description on the non-conformity</i>	Type of CAPAs - Tick as many as applicable <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up

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

² A new row with the information indicated in this section should be repeated for each condition on designation.

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

		<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	Implementation of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA³/remarks:	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
2.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		Additional description of CAPA/remarks:	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
3.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
Quality management system requirements			
4.		Type of CAPAs - Tick as many as applicable <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up

³ 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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		<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	Implementation of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
5.		Type of CAPAs - Tick as many as applicable <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	Non-conformity
			<input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			Implementation of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
Resource requirements			
6.		Type of CAPAs - Tick as many as applicable <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	Non-conformity
			<input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			Implementation of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA
			<input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
7.		Type of CAPAs - Tick as many as applicable <input type="checkbox"/> Change of procedure(s) <input type="checkbox"/> Revision of existing procedures <input type="checkbox"/> Creation of new/additional QMS document(s)	Non-conformity
			<input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
			Implementation of CAPA

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

		<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
		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
8.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		Additional description of CAPA/remarks::	Implementation of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
Process requirements			
9.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
		Additional description of CAPA/remarks::	Implementation of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
10.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up
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		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
11.		Type of CAPAs - Tick as many as applicable <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	Non-conformity <input type="checkbox"/> Closed <input type="checkbox"/> To be followed-up Implementation of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation
		Additional description of CAPA/remarks::	Effectiveness of CAPA <input type="checkbox"/> Already verified <input type="checkbox"/> To be verified following designation