**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 | **☐** |
| **Date of follow up on-site assessment (if applicable)** |  | Renewal of designation | **☐** |
| Scope extension | [ ]  |
| **Regulation** | **Tick** |
| **Regulation (EU) 745/2017** | **☐** |
| **Regulation (EU) 746/2017** | **☐** |

|  |
| --- |
| **Summary of the designating authority assessment** |
| **Brief description of the assessment carried out by the designating authority** |
| *Please provide a summary of the result of the assessment carried out by the designating authority* |
| **Have all corrective and preventive actions been appropriately addressed and, where required, implemented?** | Yes | [ ]  |
| No | [ ]  |
| *Provide a justification if the answer is NO* |

|  |
| --- |
| **Remaining diverging opinions** |
| **Is there any remaining diverging opinion with the JAT?**  | Yes | [ ]  |
| No | [ ]  |
| **1** | *If applicable, please provide information on any remaining diverging opinions with the JAT including***[[1]](#footnote-1)***:**- designating authority's opinions raised on-site, and**- any updates to these opinions*  |
| **2** | *See above*  |

|  |
| --- |
| **Designating authority recommendation for designation (Tick as applicable)** |
| [ ]  Designation of the CAB / NB **not** recommended [ ]  Designation of the CAB / NB recommended[ ]  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]](#footnote-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**")  | **☐** |
| See appended form <insert file name> (based on "NBOG F **2017-4**") | **☐** |
| [ ]  Scope of designation proposed by designating authority is the **same** as that applied for by the CAB / NB[ ]  Scope of designation proposed by designating authority is **different** to that applied for by the CAB / NB |
| *In case the scope of designation proposed differs in respect to the applied for scope please provide an explanation:* |

|  |
| --- |
| **List of non-conformities and designating authority's aassessment 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** |
|  | *Description on the non-conformity* | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA***[[3]](#footnote-3)***/remarks:** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks:** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Quality management system requirements** |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Resource requirements** |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) ☐ Rework of project file(s)[ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Process requirements** |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
|  |  | **Type of CAPAs -** *Tick as many as applicable*[ ]  Change of procedure(s)[ ]  Revision of existing procedures[ ]  Creation of new/additional QMS document(s)[ ]  Training of personnel[ ]  Rework of personnel file(s) [ ]  Rework of project file(s) [ ]  Contract with new internal / external personnel[ ]  CAPA insufficient / missing | **Non-conformity** |
| [ ] Closed[ ]  To be followed-up |
| **Implementation of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |
| **Additional description of CAPA/remarks::** | **Effectiveness of CAPA** |
| [ ] Already verified[ ]  To be verified following designation |

1. A new row with the information indicated in this section should be repeated for each diverging opinion. [↑](#footnote-ref-1)
2. A new row with the information indicated in this section should be repeated for each condition on designation. [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)