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) | | | | |
| B. d. and an all an articles are all artic | | Purpose of the assessment | | Tick |
| Date of on-site assessment | | Initial designation | | |
| Date of follow up on-site | | Renewal of designation | | |
| assessment (if applicable) | | 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 | | | | |
| 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 | Yes | ; | |
| Have all corrective and preventive actions been appropriately addressed and, where required, implemented? | | | | |
| Provide a justification if the answer is NO | | • | | |

| Remaining diverging opinions | | | | | |
|--|---|---|----------------|----------|--|
| Is there any remaining diverging opinion with the JAT? | | d. d 14T0 | Yes | | |
| | | No | | | |
| | If applicable, please provide info | ormation on any remaining diverging opinions with the JAT | including¹: | | |
| 1 | - designating authority's opinions raised on-site, and - any updates to these opinions | | | | |
| | | | | | |
| 2 | See above | | | | |
| Desig | nating authority recommenda | tion for designation (Tick as applicable) | | | |
| ☐ Des | ignation of the CAB / NB not recommend | ded | | | |
| ☐ Des | ignation of the CAB / NB recommended | | | | |
| ☐ Des | ignation of the CAB / NB recommended | with the following condition(s): | | | |
| 1 | Provide information on any cond | litions to be established as part of the designation ² | | | |
| 2 | See above | See above | | | |
| | | | | | |
| Desig | nating authority recommende | d scope of designation (Tick as, and if, applic | cable) | | |
| See appended form <insert file="" name=""> (based on "NBOG F 2017-3") □</insert> | | | | | |
| See appended form <insert file="" name=""> (based on "NBOG F 2017-4")</insert> | | | | | |
| ☐ Scope of designation proposed by designating authority is the <u>same</u> as that applied for by the CAB / NB | | | | | |
| ☐ Scope of designation proposed by designating authority is <u>different</u> to that applied for by the CAB / NB | | | | | |
| In case | the scope of designation proposed diffe | rs in respect to the applied for scope please provide an expl | anation: | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| 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 | | |
| | • | | designating at | uthority | |
| Organi | sational and general requirements | 1 | designating a | uthority | |
| Organi 1. | | Type of CAPAs - Tick as many as applicable | Non-confor | , | |

 $\hfill \square$ Revision of existing procedures

☐ 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.

| | | ☐ Creation of new/additional QMS document(s) | Implementation of |
|---------|--------------------------------|---|--|
| | | ☐ Training of personnel | Implementation of CAPA |
| | | Rework of personnel file(s) | ☐ Already verified |
| | | ☐ Rework of project file(s) | ☐ To be verified |
| | | ☐ Contract with new internal / external personnel | following designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA³/remarks: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | ☐ To be verified |
| | | | following designation |
| 2. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | ☐ Change of procedure(s) | ☐ Closed |
| | | ☐ Revision of existing procedures | \square To be followed-up |
| | | ☐ Creation of new/additional QMS document(s) | Implementation of |
| | | ☐ Training of personnel | CAPA |
| | | ☐ Rework of personnel file(s) | ☐ Already verified |
| | | ☐ Rework of project file(s) | ☐ To be verified |
| | | ☐ Contract with new internal / external personnel | following designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | ☐ To be verified |
| | | | following designation |
| 3. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | ☐ Change of procedure(s) | ☐ Closed |
| | | Revision of existing procedures | ☐ To be followed-up |
| | | ☐ Creation of new/additional QMS document(s) | Implementation of |
| | | ☐ Training of personnel | CAPA |
| | | Rework of personnel file(s) | ☐ Already verified |
| | | Rework of project file(s) | ☐ To be verified following designation |
| | | Contract with new internal / external personnel | Tollowing designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks:: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | ☐ To be verified |
| Quality | management system requirements | | following designation |
| 4. | management system requirements | Time of CADAs. Tick as magnings and limble | Non ourfamelte. |
| 4. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | Change of procedure(s) | ☐ Closed |
| | | Revision of existing procedures | ☐ 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.

| | | ☐ Creation of new/additional QMS document(s) ☐ Training of personnel | Implementation of CAPA |
|--------|------------------|--|---|
| | | Rework of personnel file(s) | ☐ Already verified |
| | | Rework of project file(s) | ☐ To be verified |
| | | ☐ Contract with new internal / external personnel | following designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks:: | Effectiveness of CAPA |
| | | · | ☐ Already verified |
| | | | ☐ To be verified |
| | | | following designation |
| 5. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | ☐ Change of procedure(s) | ☐ Closed |
| | | ☐ Revision of existing procedures | ☐ To be followed-up |
| | | ☐ Creation of new/additional QMS document(s) | Implementation of |
| | | ☐ Training of personnel | CAPA |
| | | ☐ Rework of personnel file(s) | ☐ Already verified |
| | | ☐ Rework of project file(s) | ☐ To be verified |
| | | ☐ Contract with new internal / external personnel | following designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks:: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | |
| | | | ☐ To be verified following designation |
| Resour | rce requirements | | |
| Resour | rce requirements | Type of CAPAs - Tick as many as applicable | |
| | rce requirements | Type of CAPAs - Tick as many as applicable ☐ Change of procedure(s) | following designation |
| | rce requirements | | following designation Non-conformity |
| | rce requirements | ☐ Change of procedure(s) | Non-conformity Closed |
| | rce requirements | ☐ Change of procedure(s) ☐ Revision of existing procedures | Non-conformity Closed To be followed-up |
| | rce requirements | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) | Non-conformity Closed To be followed-up Implementation of CAPA Already verified |
| | rce requirements | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel | Non-conformity Closed To be followed-up Implementation of CAPA Already verified To be verified |
| | rce requirements | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) | Non-conformity Closed To be followed-up Implementation of CAPA Already verified |
| | rce requirements | □ 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) | Non-conformity Closed To be followed-up Implementation of CAPA Already verified To be verified |
| | rce requirements | □ 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 | Non-conformity Closed To be followed-up Implementation of CAPA Already verified To be verified |
| | rce requirements | □ 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 |
| | rce requirements | □ 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 Effectiveness of CAPA |
| | rce requirements | □ 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 Effectiveness of CAPA Already verified To be verified |
| 6. | rce requirements | ☐ 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 Additional description of CAPA/remarks:: | Non-conformity Closed To be followed-up Implementation of CAPA Already verified following designation Effectiveness of CAPA Already verified To be verified following designation |
| 6. | rce requirements | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: | Non-conformity Closed To be followed-up Implementation of CAPA Already verified following designation Effectiveness of CAPA Already verified following designation Non-conformity |

| | | ☐ Training of personnel | ☐ Already verified |
|--------|-----------------|---|--|
| | | ☐ Rework of personnel file(s) | ☐ To be verified |
| | | ☐ Rework of project file(s) | following designation |
| | | ☐ Contract with new internal / external personnel | |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks:: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | ☐ To be verified |
| | | | following designation |
| 8. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | ☐ Change of procedure(s) | ☐ Closed |
| | | ☐ Revision of existing procedures | ☐ To be followed-up |
| | | ☐ Creation of new/additional QMS document(s) | Implementation of |
| | | ☐ Training of personnel | CAPA |
| | | ☐ Rework of personnel file(s) | ☐ Already verified |
| | | ☐ Rework of project file(s) | ☐ To be verified |
| | | ☐ Contract with new internal / external personnel | following designation |
| | | ☐ CAPA insufficient / missing | |
| | | Additional description of CAPA/remarks:: | Effectiveness of CAPA |
| | | | ☐ Already verified |
| | | | ☐ To be verified |
| | | | following designation |
| Proces | ss requirements | | |
| | | | |
| 9. | | Type of CAPAs - Tick as many as applicable | Non-conformity |
| | | Type of CAPAs - Tick as many as applicable ☐ Change of procedure(s) | Non-conformity ☐ Closed |
| | | | |
| | | ☐ Change of procedure(s) | ☐ Closed |
| | | ☐ Change of procedure(s) ☐ Revision of existing procedures | ☐ Closed ☐ To be followed-up |
| | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) | ☐ Closed ☐ To be followed-up Implementation of |
| | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel | ☐ Closed ☐ To be followed-up Implementation of CAPA |
| | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified |
| | | □ 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) | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified |
| | | □ 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 | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified |
| | | □ 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 | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation |
| | | □ 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 | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation Effectiveness of CAPA |
| | | □ 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 | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation Effectiveness of CAPA ☐ Already verified |
| | | □ 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 | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation Effectiveness of CAPA ☐ Already verified ☐ To be verified ☐ To be verified |
| 9. | | □ 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 Additional description of CAPA/remarks:: | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation Effectiveness of CAPA ☐ Already verified ☐ To be verified following designation |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: | ☐ Closed ☐ To be followed-up Implementation of CAPA ☐ Already verified ☐ To be verified following designation Effectiveness of CAPA ☐ Already verified ☐ To be verified following designation Non-conformity |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: Type of CAPAs - Tick as many as applicable □ Change of procedure(s) | □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified following designation Effectiveness of CAPA □ Already verified □ To be verified following designation Non-conformity □ Closed |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: Type of CAPAs - Tick as many as applicable □ Change of procedure(s) □ Revision of existing procedures | □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified following designation Effectiveness of CAPA □ Already verified □ To be verified following designation Non-conformity □ Closed □ To be followed-up |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: Type of CAPAs - Tick as many as applicable □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) | □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified following designation Effectiveness of CAPA □ Already verified □ To be verified following designation Non-conformity □ Closed □ To be followed-up Implementation of |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: 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 | □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified following designation Effectiveness of CAPA □ Already verified □ To be verified following designation Non-conformity □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified |
| 9. | | □ Change of procedure(s) □ Revision of existing procedures □ Creation of new/additional QMS document(s) □ Training of personnel □ Rework of personnel file(s) □ Contract with new internal / external personnel □ CAPA insufficient / missing Additional description of CAPA/remarks:: 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) | □ Closed □ To be followed-up Implementation of CAPA □ Already verified □ To be verified following designation Effectiveness of CAPA □ Already verified □ To be verified following designation Non-conformity □ Closed □ To be followed-up Implementation of CAPA □ Already verified |

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

| | Additional description of CAPA/remarks:: | | Effectiveness of CAPA | |
|-------------------------------|--|---|--------------------------|--|
| | | | ☐ Already verified | |
| | | | \square To be verified | |
| | | | following designation | |
| 11. | | Type of CAPAs - Tick as many as applicable | Non-conformity | |
| | ☐ Change of procedure(s) | ☐ Change of procedure(s) | , | |
| | | ☐ Revision of existing procedures | ☐ Closed | |
| | ☐ Creation of new/additional QMS document(s) | \square To be followed-up | | |
| | ☐ Training of personnel | Implementation of | | |
| ☐ Rework of personnel file(s) | ☐ Rework of personnel file(s) | CAPA | | |
| | | ☐ Rework of project file(s) | ☐ Already verified | |
| | | ☐ Contract with new internal / external personnel | ☐ To be verified | |
| | | ☐ CAPA insufficient / missing | following designation | |
| | Additional description of CAPA/remarks:: | Effectiveness of CAPA | | |
| | | | ☐ Already verified | |
| | | | ☐ To be verified | |
| | | | following designation | |