Annex I: Template CAPA plan and assessment thereon

**PART I: Basic information**

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| **BASIC INFORMATION** | | | |
| **Name of the national authority responsible for notified bodies: designating authority (DA)** | | | |
|  | | | |
| **Name of the applicant conformity assessment body (CAB) or notified body (NB) (with the identification number)** | | | |
|  | | | |
| **Reference number(s)** | **DA** |  | |
| **DG SANTE F5** |  | |
| **Date(s) of the on-site assessment** | |  | |
| **Type of assessment** | | MDR | IVDR |
|  | | designation | |
| re-assessment | |
| extension of the scope of designation | |
| challenge to the competence of the notified body[[1]](#footnote-2) | |
| **DA’s lead assessor** | |  | |
| **JAT coordinator** | |  | |

**PART II: CAPA plan and assessment thereon** (to be copied and completed for each NC)

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| --- | --- | --- | --- |
| **CONFORMITY ASSSESSMENT BODY/ NOTIFIED BODY**  *Where documents are provided, ensure they are clearly referenced, the document file names are understandable for the DA and JAT and the content is clear. Any abbreviations and acronyms should be explained upon first use.* | | | |
| **Non-compliance (NC)** | | | |
| **NC No:** | ……. of ……. | **Classification of the finding:** | Major NC |
| Minor NC |
| **NB’s reference:** |  | Observation |
| *Insert NC details exactly as worded by the DA, without any modification: wording, legal reference and classification. Include the official DG SANTE translation of the NCs, if applicable and provided*.  *Note that an observation (section 2.2.4 of MDCG 2022-13) is a finding that does not breach any legal requirement. While the NB may address observations, the DA may have specific expectations. The JAT will not review actions related to observations.* | | | |
| **Legal reference:** |  | | |
| **Correction(s)** | | | |
| *Indicate the action(s) taken to eliminate the detected NC (also refer to section 4.1 for further guidance)*  *Provide evidence of implementation (documents or adequate information) of the described correction(s) and containment action(s).* | | | |
| **Implementation target date:** | . . / . . / . . . . | **Responsibility:** |  |
| **Root cause(s)** | | | |
| *Describe the outcome of the investigation of the NC, considering both the classification and the extent of the NC (e.g. single occurrence, reoccurrence, systemic issue) and identify the underlying cause(s). Refer to section 4.2 for further guidance.*  *If applicable, also describe any potential causes that could lead to similar or related NCs.* | | | |
| **Corrective and preventive actions** | | | |
| *Provide a detailed description of the corrective action(s), i.e. the action(s) taken to eliminate the root cause(s) to prevent recurrence. Corrective action(s) should be appropriate to the classification of the NC.*  *Provide evidence whenever relevant (e.g. in case of CAPAs linked to major NC).*  *If applicable, provide a description of any preventive actions, i.e. any action(s) taken to eliminate the cause of a potential similar or related NC.*  *(Also refer to section 4.3. for further guidance).* | | | |
| **Implementation target date:** | . . / . . / . . . . | **Responsibility:** |  |
| **Actions for verification of effectiveness** | | | |
| *Provide a detailed description of the action(s) planned and the criteria which will be used for the verification of effectiveness of the implemented corrective and preventive actions.*  *(Also refer to section 3.4 for further guidance).* | | | |
| **Implementation target date:** | . . / . . / . . . . | **Responsibility:** |  |
| **DESIGNATING AUTHORITY** | | | |
| **Assessment, confirmation and opinion** | | | |
| *Detail the assessment to determine if the NC has been appropriately addressed by the NB in the CAPA plan, based on the provided information and any necessary evidence. Indicate whether the actions described, and information provided, by the NB are deemed satisfactory before confirming the CAPA plan related to this NC.*  *If the CAPA plan related to this NC cannot yet be confirmed and is therefore classified as unsatisfactory, explain the rationale for this classification, specify the elements needing further clarification and/or additional information required from the NB, including applicable deadlines. Request within a specified timeframe the NB for a revised CAPA plan, addressing the above-mentioned issues (see also section 2.3.2 of MDCG 2022-13).*  *(For additional guidance, see section 4)* | | | |
| **Assessment and confirmation date(s):** | . . / . . / . . . . | **Opinion:** | Satisfactory |
| Unsatisfactory |
| **Assessment of the implementation, where appropriate** | | | |
| *Where appropriate, insert details of assessment of implementation of CAPAs here, or write ‘Not applicable’ if not relevant.* | | | |
| **Assessment date(s):** | . . / . . / . . . . | **Opinion:** | Satisfactory |
| Unsatisfactory |

1. Article 47(3) MDR or 43(3) IVDR assessment [↑](#footnote-ref-2)