Annex II: Template JAT review of the CAPA and the DA’s opinion

*The JAT will indicate whether it agrees with the DA’s opinion, if clarifications are needed, or if any of the actions are not deemed as acceptable and therefore a modified CAPA plan should be submitted. An explanation should be provided in the latter cases.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **JAT's review of the CAPA and the DA’s opinion thereon** | | | | | |
| **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) of the Joint Assessment** | | **DA** |  | | |
| **DG SANTE F5** |  | | |
| **Date(s) of the on-site assessment** | | |  | | |
| **Type of assessment** | | | MDR | IVDR | |
|  | | | designation | | |
| re-assessment | | |
| extension | | |
| challenge to the competence of the notified body[[1]](#footnote-2) | | |
| **DA’s lead assessor** | | |  | | |
| **JAT coordinator** | | |  | | |
| **Current review** | | | | | |
| **Date of JAT's review:** | | | . . / . . / . . . . | | |
| **Reference to the latest D.A. response (e.g. Ares number):** | | |  | | |
| **General comments and/or comments related to all NCs (if applicable)** | | | | | |
|  | | | | | |
| **JAT review of the CAPA and the DA’s opinion thereon** | | | | | |
| **NC#** | **JAT Comment** | | | | **Acceptance[[2]](#footnote-3)** |
|  |  | | | | Closed  Not (yet) closed |
|  |  | | | | Closed  Not (yet) closed |

1. Article 47(3) MDR or 43(3) IVDR assessment [↑](#footnote-ref-2)
2. See section 6 in the guidance: if ‘Closed’, the JAT accepts the CAPA plan and the DA’s opinion thereon for this NC. In the other case, the JAT motivates a request for further clarification or modification of this CAPA plan. [↑](#footnote-ref-3)