**Auditing Organization** **Click here to enter text.**

Date of receipt of the application Click here to enter a date.

**Application Screening Checklist**

|  |  |  |
| --- | --- | --- |
| Criteria | Review by RAC Secretariat |  Review by Assessment Program Manager |
|  | Yes | No | Yes | No | Needs Clarification |
| 1. Eligibility in accordance with clause 5.1 of IMDRF/MDSAP WG/N3 2nd edition |[ ] [ ] [ ] [ ] [ ]
| 2. Demonstrated financial stability over past 3 years |[ ] [ ] [ ] [ ] [ ]
| 3. Available auditing resources ≥ 150% of current demand |[ ] [ ] [ ] [ ] [ ]

**Note: The application should not be reviewed any further unless all three mandatory criteria above are met.**

**Application Review Check List**

|  |  |  |
| --- | --- | --- |
| Application Section | Review by RAC Secretariat | Review by Assessment Program Manager |
|  | Complete | Incomplete | Not Applicable | Acceptable | Not Acceptable | Needs Clarification | Not Applicable |
| 1. AO information |[ ] [ ]   |[ ] [ ] [ ]   |
| Address of AO Head Office (if different) |[ ] [ ] [ ] [ ] [ ] [ ] [ ]
| 2. Contact information |[ ] [ ]   |[ ] [ ] [ ]   |
| Proof of legal status as a legal entity and date obtained | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Proof of adequate com-mercial liability insurance | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Annual report | [ ] Attached | [ ] Not Attached |[ ] [ ] [ ] [ ] [ ]
| List and date of accredita-tions or other recognitions for medical device audits  | [ ] Attached | [ ] Not Attached |[ ] [ ] [ ] [ ] [ ]
| 3. Corporate information |[ ] [ ]   |[ ] [ ] [ ]   |
| 4. Critical location information |[ ] [ ]   |[ ] [ ] [ ]   |
| Separate critical location information form |[ ] [ ] [ ] [ ] [ ] [ ] [ ]
| 5. Organization information |[ ] [ ]   |[ ] [ ] [ ]   |
| 6. Medical device technical areas |[ ] [ ]   |[ ] [ ] [ ]   |
| 7. Contractual arrangements with external organizations |[ ] [ ]   |[ ] [ ] [ ]   |
| Signature |[ ] [ ]   |[ ] [ ] [ ]   |
| Auditing Organization (AO) application matrix |[ ] [ ]   |[ ] [ ] [ ]   |
| Management system documentation | [ ] Attached | [ ] Not Attached (not Blocking) |[ ] [ ]  [ ] Select if documentation was not provided  |
| Statement on letterhead paper and signed by senior management agreeing to conduct regulatory audits in conformance with MDSAP requirements | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Identification of branches, regional and/or national offices and any related bodies authorized to conduct regulatory audits and issue MDSAP certification documents | [ ] Attached | [ ] Not Attached |[ ] [ ] [ ] [ ] [ ]
| List identifying the AO personnel or committee members making decisions under the MDSAP | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Auditor and technical expert competency summary | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Draft contract between the AO and the manufacturer | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Sample of certification document | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |
| Template of contractual agreement with external organizations | [ ] Attached | [ ] Not Attached |[ ] [ ] [ ] [ ] [ ]
| Procedures for information exchange between the AO and the RAs under MDSAP | [ ] Attached | [ ] Not Attached |  |[ ] [ ] [ ]   |

**Conclusion of the Review on the Acceptability of the Application**

[ ] Acceptable 🡪 proceed with the assessment program processes

[ ] Not Acceptable

[ ] Needs Clarifications:

Specifically:

 Click here to enter text.

Decision on whether to proceed with the assessment program process considering the need for clarifications:

Click here to enter text.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature |  |  |  |
| Date | Click here to enter a date. | Click here to enter a date. | Click here to enter a date. |
| Function | RAC Secretariat Check of completeness of the application | Assessment Program Manager Endorsement of the conclusion | Lead Project Manager Endorsement of the conclusion if either:* not acceptable, or
* proceed with the assessment program despite the need for clarification
 |