Submission of this form indicates a request for certification, or continued certification, with TUV USA, Inc. Additional information may be required in order to provide a quotation.

# **Section 1: HEADQUARTERS INFORMATION**

***Additional site information captured in Section 4***

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | |
| **Company Name (Legal Entity):** | | | | | | **Date:**  **Form Completed By:** | | | | | |
| Street Address: | | | | | | City: | | State: | | Zip: | Country: |
| Phone: | | | | Fax: | | Website: | | | | | |
| **L** | | | | | | | | | | | |
| **Mr./Ms./Mx.** | **Main Contact Name:** | | | | | **Title:** | | | | | |
| Office (Direct Line or Extension): | | | Mobile/Cell: | | | Email Address: | | | | | |
| **Mr./Ms./Mx.** | **Accounts Payable Contact Name:** | | | | | **Title:** | | | | | |
| Office (Direct Line or Extension): | | | Mobile/Cell: | | | Email Address: | | | | | |
|  | | | | | | | | | | | |
| *Please list below only information associated with the headquarters. Additional site information is captured in Section 4.* | | | | | | | | | | | |
| **Number of Shifts:** | | **Shift Time(s):**  Shift 1:  Shift 2:  Shift 3: | | **Total Number of Employees:** | **# of Employees Per Shift:**  Shift 1:  Shift 2:  Shift 3: | | **# of QA-Staff:** | | | | |
| **# of Full Time Employees:** | | **# of Part Time / Temporary Employees:** | | |
| **What processes is the HQ responsible for?** | | | | | | | | | | | |

# **Section 2: MANUFACTURING INFORMATION**

|  |  |
| --- | --- |
|  | |
| **What manufacturing processes are handled in-house (i.e. molding, machining, welding, assembly, etc.)?** | **Please check off the relevant manufacturing processes that are subcontracted:**  Component manufacturing  Sterilization  Coating/Painting/Anodizing  Finishing  Sub-assembly  Labelling/Packaging  Software Development  Other (please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
| **Are any manufacturing processes subcontracted/outsourced?**  All manufacturing processes are subcontracted  Some manufacturing processes are subcontracted  No manufacturing processes are subcontracted  *If any processes are subcontracted/outsourced, please complete the MF 120-A3 Critical Suppliers List.* |
| **What non-manufacturing processes are handled in-house (i.e. sales, customer support, etc.)?** | **What non-manufacturing processes are subcontracted/outsourced?**  Research  Design & Development  Sales/Marketing  Other (please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  *If any processes are subcontracted/outsourced, please complete the MF 120-A3 Critical Suppliers List.* |
| **Additional information/services/requests:** | |

# **Section 3: QUALITY SYSTEM INFORMATION**

|  |  |  |
| --- | --- | --- |
|  | | |
| **Please indicate which standards you are applying for:** | | |
| ***Standards offered under TUV USA, Inc. Accreditation or Recognition:***  ISO 13485:2016  ISO 13485:2016 under MDSAP  ***If you are applying for MDSAP, please indicate which jurisdictions you are applying for:***  Australia  Brazil  Canada  Japan United States  ***MDSAP Affiliate member’s jurisdictions you are applying for:***  South Korea | ***Standards offered under TÜV NORD CERT Accreditation:***  EN ISO 13485:2016  MDD 93/42/EEC Annex \_\_ (Pls. Specify)  *[applications for new MDD certifications will not be accepted after Jun. 30, 2019]*  *Please be aware that if you are applying for the above standards, additional questionnaires/applications may be required.* | |
| **Other (please specify):** | | |
| If you are applying for ISO 13485:2016, EN ISO 13485:2016, and/or MDD 93/42/EEC, please submit a completed **MF 120-A1 Product List**.  If you are applying for MDSAP, please submit a completed **MF 120-A2 Product Registrations and Establishment License** Excel sheet. | | |
|  | | |
| **What countries are these devices sold to (i.e. US, Canada, Europe, etc.)?** [please include current and planned jurisdictions] | | |
| **Are you responsible for the design of your product(s)?**  Yes  No | | |
| **List any non-applicable clauses of ISO 13485:** | | |
| **Desired scope of certification / Current scope of certification:** | | |
|  | | |
| **Weare a *CURRENT CUSTOMER* of TUV USA, Inc.** | | |
|  | | |
| **We *ARE* currently registered to a management standard by a different Certification Body/Notified Body/Auditing Organization and are requesting to transfer**  *Please provide a copy of your current certificate and the audit reports from the most recent audit cycle when submitting this application* | | |
| **Which standard(s) are you currently registered to?** | | **What is the expiration date of your current certificate(s)?** |
| **When was your last audit?**  **What type of audit was conducted (i.e. Re-Certification, Surveillance 1, Surveillance 2, etc.)?** | | **What surveillance scheme are you current using?**  Semi-Annual  Annual  Other (please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
| **When is the next scheduled activity with your current registrar?** | | **What is the reason for transfer:** |
|  | | |
| **We are *NOT* currently registered to a management standard** | | |
| If no, what percentage is implemented? ­­­­\_\_\_\_\_\_\_\_ % | | |
|  | | |
| **Was a consultant used to develop/implement your Quality Management System?**  Yes  No | | |
| **If yes, please provide the name of the consultant/firm:** | | |
|  | | |
| **When would you prefer to have your audit?**  *Please be aware that we will do our best to accommodate your request, however we cannot finalize dates until after the contract has been signed.* | | |
| **Stage 1:** | | **Stage 2:** |
| *Stage 1 is required for all initial certifications. We recommend a minimum of 4 weeks between Stage 1 and Stage 2 to ensure that there is enough time to resolve findings from the Stage 1 audit. If findings cannot be closed prior to the Stage 2 audit, it will result in the cancellation and rescheduling of the Stage 2 audit. If there is a gap of more than 3 months between the Stage 1 and Stage 2 audit, the Stage 1 audit must be re-conducted, and additional fees may apply.* | | |

# **Section 4: ADDITIONAL SITES**

*Copy below table as needed*

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | | |
| **Location Name (Legal Entity):** | | | | | | | | | | | |
| Street Address: | | | | | | City: | | State: | Zip: | | Country: |
|  | | | | | | | | | | | |
| **Mr./Ms./Mx.** | **Contact Name (if different from main contact):** | | | | | **Title:** | | | | | |
| Office (Direct Line or Extension): | | | Mobile/Cell: | | | Email Address: | | | | | |
|  | | | | | | | | | | | |
| *Please list below only information associated with this location* | | | | | | | | | | | |
| **Number of Shifts:** | | **Shift Time(s):**  Shift 1:  Shift 2:  Shift 3: | | **Total Number of Employees:** | **# of Employees Per Shift:**  Shift 1:  Shift 2:  Shift 3: | | **# of QA-Staff:** | | | | |
| **# of Full Time Employees:** | | | **# of Part Time / Temporary Employees:** | |
| **What processes is this location responsible for?** | | | | | | | | | | | |
| **Desired Scope / Current scope for this site:** | | | | | | | | | | | |
| **Do you want a sub-certificate for this location?**  Yes, add on a sub-certificate *(additional certificate fees will apply)*  No, include on an annex to the main certificate *(no additional certificate fees will apply)* | | | | | | | | | | | |
| **Additional information:** | | | | | | | | | | | |

# **Section 6: OTHER**

|  |
| --- |
|  |
| **How did you hear about TUV USA, Inc./TÜV NORD Group?** |
|  |
| **Confidentiality Notice:**  Information provided in this application, attached annexes, and as additional supportive documents will kept confidential and only shared when legally required with recognized regulatory authorities or accreditation bodies. Data collected by TUV USA, Inc. will never be sold. |
| **Notes from TUV USA:**   * Offers are valid for 6 months after issuance. If they are not signed in that 6-month period, applications will need to be resubmitted and the offer re-calculated. * If TUV USA, Inc. accepts this application, the most current versions of the contract documents available will be provided. * If a contract (MF 170, MF 110, A00F061) is signed, the applicant must immediately notify the competent authorities and TUV USA, Inc. in the case of: * Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to, or have led to, the injury or death of a patient or user; and * Any technical or medical reason connected with the characteristics or performance of a device leading to the injury or death of a patient or user that has led to a systematic recall of devices of the same type by the manufacturer. |

# **TUV USA, Inc. Official Use Only**

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|  | | | | |
| **Audit Type :** | CA  RC  SA1  SA2  SA3  SA4  SPA  UAA  If multiple checked, please clarify: | | | |
| **EA Code(s):** | | | **NANDO Code(s):** | |
| **Technical Area (per IAF MD 9):** | | | **Is the Technical Area within the scope of Accreditation (ANAB / TNC DAkkS / ZLG)?**  Yes  No | |
| **Technical Area (per IMDRF/MDSAP WG/N4 Final:2013):** | | | **Is the Technical Area within the scope of MDSAP Recognition?**  Yes  No | |
| **Does the information submitted by the customer in this questionnaire impact the previously assigned code(s) / technical area(s)?**  Yes  No | | | **If yes, detail change:** | |
|  | | | | |
| **Design and Non-Applicability information provided :** | | Yes  No | | |
| **Relevant Annexes provided :** | | Yes  No | | |
| Which ones were provided?  MF 120-A1 List of Products  MF 120-A2 Product Registrations and Establishment Licenses  MF 120-A3 Critical Suppliers List | | |
| **Suggested Audit Team :** | | **Lead Auditor :** | |  |
| **Co-Auditor(s) :** | |  |
| **Suggested Technical File Reviewer (ISO – under ANAB and / or MDSAP) :** | |  | | |
| **Required Contract Document(s) :** | | MF 110 ISO 13485 Contract  MF 170 MDSAP Contract  MF 184 General Medical Offer  MF 185 Terms and Conditions  A00F061 TNC Offer and Documents | | |
|  | | | | |
| **Additional Comments (enter below) :** | | | | |
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|  | **TUV USA, Inc. Official Use Only** | | |  |
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|  |  |  |  |  |
|  | Date |  | Authorized Signatory |  |
|  | *Signature indicates that this application has been reviewed and accepted by TUV USA, Inc.* | | |  |

**Revision History for MF120:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Description** | **Effective date** | **Training** |
| 14 | *Major re-write from the previous version and removed obsolete information like CMDCAS* | 2020.02.10 | PM, auditors, technical experts & File reviewers  notification |
| 15 | * Added “Mr./Ms./Mx.” to contact names * Official Use Only section: Corrected the review table to be more clear in capturing code / technical area confirmation, and confirmation if a change needs to be made * Official Use Only section: Added confirmation if the identified scopes are covered under the Accreditation certificate / MDSAP Recognition * Added Accounts Payable Information | 2020.03.01 | Technical experts will be communicated to ensure that a confirmation of the customer’s codes / technical areas occurs with each review of the MF 173.  Finance Department will be informed of update to form. |