|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **一、Organization’s Basic Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1、Organization’s name | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2、Registered address | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3、Business address | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Zip Code | | |  | |
| 4、Contact Person | |  | | | | | | | | | | | | | | Title | | |  | | | | | | | | | | | | | | | | Tel | | | | | | |  | | | | | | | | | | | | |
| E-mail | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5、Working language | | | | | | | | | | | | | | Chinese  English  Other | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| 1. **Organization’s Basic Information for Certification Application** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1、Certification standards, Accreditation symbol, Certification types | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Certification Standards** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **Accreditation Symbol** | | | | | | | | | | | | | | | **Certification Types** | | | | | | | | | | |
| Quality Management System  GB/T 19001-2016/ISO 9001:2015  GB/T 50430-2017 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Environmental Management System  GB/T 24001-2016/ISO 14001:2015 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Occupational Health and Safety Management System  GB/T 45001-2020/ISO 45001:2018 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Medical Device Quality Management System  GB/T 42061-2022/ISO 13485:2016 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Information Security Management System  GB/T 22080-2016/ISO 27001：2013  ISO 27001:2022 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Food Safety Management System  ISO 22000:2018 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| HACCP Certification Rules（V1.0） | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Cosmetics Quality Management System  ISO 22716:2007  GMPC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Business Continuity Management System  GB/T 30146-2023/ISO 22301:2019 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Integrity management system of enterprise  GB/T 31950-2023 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Asset Management System  GB/T 33173-2016/ISO 55001:2014 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Hazardous Substance Process Management System  IECQ QC080000:2017 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | IECQ  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Security Management System for the Supply Chain  ISO 28000:2022 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | CNAS  ANAB  IAS  Other | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| Other： | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Initial certification  Transfer  Recertification | | | | | | | | | | |
| 2、Establishment and operation of the organization management system: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. A documented management system has been established: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | | | | | | | | | | |
| 1. Whether they comply with statutory and regulatory requirements have been identified and evaluated: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | | | | | | | | | | |
| 1. Whether the internal audit and management review have been completed: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | | | | | | | | | | |
| 1. The time wish to conduct on-site audit is: | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Total number of employees | | | | | |  | | | | | | | | | | | Total number of employees covered by the management system | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | Including: | | | | | | |
| a）Permanent staff | | | | | |  | | | | | | | | | | | Non-fixed personnel (e.g.contractor’s personnel) | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | Number | | |
| b）Is there a shift | | | | | | No  Yes, please specify as follows | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Number of shifts | | | |  | | | | | | | | | Staff number per shift | | | | | | | | | |  | | | | | | | | Main process/activity: | | | | | | | | | | | | | |  | | | | | | | | | |
| The difference between the process/activity of abnormal shift (such as night shift, mid-shift) and the process/activity of normal shift (such as day shift) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| c）Number of employee working outside the organization’s workplace | | | | | | | | | | | | | | | | | | | |  | | | | | | Main process/activity: | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| *Note: Item 5) above, if any, please fill in the information according to the actual situation, if not, please fill in “0”, of which c) if any can be attached to a separate page to explain.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6）Whether have multiple-sites (including temporary sites)  No  Yes, please complete *Appendix 3* or *Appendix 4*  Note: The organizations applying for 50430, ISMS, ITSMS certification must provide the latest *list of temporary locations* before the audit planning. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **3、The scope of certification to be applied for (production, operation or service activities, information security, information technology services, corporate integrity, asset management system organizations should define the scope and boundaries based on the characteristics of the organization's business, organization, location, assets and technology; can not exceed the requirements of business licenses and administrative licenses):** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1）Inapplicable clauses and reasons (**QMS/MD only**) | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2）Outsourcing process  No  Yes, Outsourcing process: | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **For FSMS/HACCP, if there is outsourcing process:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| a）Whether the outsourcing party/processing party has established the corresponding management system and obtained the food safety management system or HACCP management system certification  No  Yes (please provide the evidence)  b）Is there mandatory requirement of laws and regulations for outsourcing  No  Yes (please provide the evidence) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3）Have you ever been certified by other certification bodies  No  Yes, please specify： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Certification body name | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Cert.status | | | | | | | |  | | | | | | |
| 1. Have you ever received any consultation related to the management system to be certified:   No  Yes, please specify： | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Consulting Agency | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Consultant name | | | | | | | | | |  | | | | |
| 1. Whether the site has a special danger area or restricted area required:   No  Yes, Area name | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| 1. The integration degree of organization’s management system   Not applicable  Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Organization has established a set of integrated documentation, including appropriate moderated operational documents when appropriate: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| b） Does the organization adopt an integrated approach to internal audits? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| c） Does the organization consider the overall business strategy and management review? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| d） Does the organization adopt an integrated approach to its policies and objectives? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| e） Does the organization adopt an integrated approach to the system process? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| f） Whether the organization has established integrated management support and management responsibilities | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| g） Whether the organization adopts an integrated approach to the improvement mechanism | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | |
| **4、**Medical Device Quality Management System (MDMS) application organization please fill in: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1）Have sterilization process or not( ISO 13485 only)  No  Yes，Sterilization method | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2） Whether the end user needs sterilization before use：  No  Yes，Sterilization method | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| 1. Belong to raw materials, spare parts or services, please fill in the Appendix 8   **5、 Information security management system(ISMS) application organization please fill in:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1）Requirements on the qualifications of certification bodies, integrity and law-abiding records or the identity background of certification personnel, as well as applicable laws and regulations related to the protection of state secrets or the maintenance of state secrets or the maintenance of national security: | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2）Consent to the accreditation body's access to information about the organization during processes such as during assessment process  Not involve  Yes  No, please state the reason: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3） Whether it has confidential and sensitive information  Not involve  Yes  No, please complete *Appendix 5* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4）Whether the certification body/organization is allowed to publish certification information on its website, including the organization name, certificate number, scope of certification, effective date, restrictions, etc. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Not involve  Yes  No, please explain | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
| 5） Whether it belongs to the Ministry of Industry and Information Technology Association [2010] No. 394 *Notice on Strengthening the security management of Information Security Management system certification* and the local and industry authorities in the requirements of the need to conduct certification record organizations.  Not involve  Yes, please submit the record information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| No, please explain | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6）Customer basic information Please fill in the *Appendix 6*  **6、Hazardous Substance Process Management System (HSPM) application organization please fill in:**  1）The company's products are：  Complete machine product  Parts  Supporting peripheral products  Other  2）The hazardous substances regulations that products need to comply with include: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| European Directive 2011/65/EU | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | European Directive 94/62/EC | | | | | | | | | | | | | | | | | | | | | | |
| European Directive 2006/66/EC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | EU ELV Directive 2000/53/EC | | | | | | | | | | | | | | | | | | | | | | |
| China RoHS 2.0 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | EU REACH | | | | | | | | | | | | | | | | | | | | | | |
| European Directive 2012/19/EU | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | ELV No.38 Notice 2015 by MIIT | | | | | | | | | | | | | | | | | | | | | | |
| Customer specified requirements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Sony  Apple | | | | | | | | | | | | | | | | | | | | | | |
| Other Identified Hazardous Substances | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3）Whether have a valid QMS certificate | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| a）  Yes，Name of the certificate issuing CB | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Whether the CB that issues the certificate is accredited?  Yes  No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Valid to | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | Last audit time | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| b)  No，  QMS Apply for QMS at the same time  Add QMS audit | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Cosmetics Quality Management System Please fill in the *Appendix 7* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Part for organization apply for Recertification：   Not involve  Yes, please fill in the following information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Whether the place of work (address) of organization name, production management or service has changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether legal status and organizational structure have been changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether the management system and important processes (including the production process) have been changed significantly | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether the employee number of organizations has been changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether the scope of certification has been changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether the corresponding laws and regulations have been changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| 1. Whether there is quality safety, environmental pollution or production safety accident | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes  No | | | | | | | | | | | | |
| **9、Is it a certificate transfer**  No  Yes, please fill in the following information | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1）Name of the previous certificate issuing CB | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2）Previous certificate status：  Suspended  Withdrew  Valid, the certificate is valid until: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| 3）The date of the last audit audit | | | | | | | | | | | |  | | | | | | | | | | Audit Type： Initial  Surveillance Recertification  Other | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |
| 4）Reason for transfer | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **三、Application materials and appendix information to be submitted (list** ***Appendix 1* attached material)** | | | |
| **四、Declaration of the applicant** | | | |
| We have obtained the public documents related to the management system certification from the official website of **POSI** (www.posicert.com), and have understood the certification fee standards, fairness requirements, certification business scope, conditions for applying for certification and general certification process, etc.  We are willing to comply with the certification requirements, provide the information needed to apply for certification and the data required by the annex, and promise to provide true and effective information and data, at the time of application has not been ordered by the law enforcement regulatory authorities to suspend business for rectification. It has not been included in the "List of seriously illegal enterprises" by the National Enterprise Credit Information Publicity System (http://gsxt.saic.gov.cn). | | | |
|  | | | |
| Representative of organization (signed) |  | |
|  |  | | |
| Organization’s name (seal) |  |
|  |  | | |
| Date |  | |

**Appendix 1: Information submitted by the management system for certification**

|  |  |  |
| --- | --- | --- |
| Basic information |  | Proof of legal status (such as business license, etc.). If the management system covers activities in multiple-sites, a copy of the legal status documents of each site (when applicable) |
|  | Valid proof of qualification. Such as production license, mandatory product certificate, safety production license, etc. involving the administrative license stipulated by laws and regulations shall submit the corresponding administrative license copy (when applicable); |
|  | At a minimum, the following documented information should be provided: policy, objectives, scope, information maintained by the organization for process operation and communication. Must provide: organization profile, organization structure (organization chart), function distribution table, process flow chart (should clearly describe key processes and special processes) and related process documents. (Can be included in manuals and program files). |
| QMS/EC9000 |  | List of technical standards, quality standards related to products/services including list of mandatory standards (**if necessary**); |
|  | List of operational documents or operational documents (applicable to GB/T 50430). |
|  | Appendix 4 List of projects under construction (applicable to GB/T 50430). |
| MDMS |  | Medical device product use description(Can be included in the registration certificate or record certificate) |
|  | Product description (for export only); |
| EMS |  | EIA report/form or record, approval, acceptance report (need to provide online record screenshot), emission permit/registration, etc. (where applicable); |
|  | List of significant environmental aspects, applicable environmental laws and regulations |
| OHSMS |  | Safety production license, safety evaluation report (when applicable) |
|  | List of significant hazards, applicable environmental laws and regulations |
|  | Detailed information of staff far away from the organization site (if applicable) Additional page |
|  | Appendix 2 OHSMS attachment. |
| ISMS |  | Risk assessment report (with a description of the risk assessment methodology); |
|  | Residual risk report; risk disposal plan; |
|  | Statement of Applicability; |
|  | Appendix 5 Declaration of Confidentiality and Sensitive Information form; |
|  | Appendix 6 Basic Information for Certified Customers. |
| FSMS/HACCP |  | Prerequisite plan, HACCP plan, OPRP plan (applicable to FSMS system); |
|  | GMP document, SSOP document, HACCP plan, food protection plan (applicable to HACCP system); |
|  | Description of the surrounding environment of the plant (water source, etc.); Plant location map, plant plan; Machining workshop plan; |
|  | Product description (including raw materials, product contact materials, processing AIDS, final products, etc.); |
|  | Process flow chart, process description; |
|  | Hazard analysis sheet, HACCP schedule (applicable to HACCP system); |
|  | Description of processing lines, seasonal production, implementation of HACCP projects and shifts; |
|  | Comply with applicable laws, regulations, standards and specifications list (name, number, release version/time) of China and the importing country (region) in the process of production, processing or service; |
|  | Production and processing equipment list and inspection equipment list; |
|  | Evidence that the product meets health and safety requirements; Where applicable, provide evidence issued by a qualified inspection agency that the water, ice and steam in contact with food meet the health and safety requirements; |
|  | Appendix 9 *List of products of the organization applying for certification* |
|  | Appendix 10 *Explanation on the Use of Food Additives*; |
|  | Annex 1: *Self-Declaration of the Applicant Organization for Certification.* |
| HSPM |  | Valid quality management system certification; |
|  | List of applicable laws, regulations and standards of the organization; |
|  | Control list of hazardous substances. |
| GMPC/22716 |  | Entrusted processing description (when applicable) |
|  | Factory location map, factory plan, processing workshop and laboratory plan, process flow chart; |
|  | A list of relevant laws, regulations, standards and specifications that are complied with (applicable) during production, processing or service; |
|  | Appendix 7 cosmetic products attachment. |
| BCMS |  | Risk assessment report； |
|  | Business continuity plan checklist; |
|  | List of standards of applicable laws and regulations. |
|  | Appendix 5 Declaration of Confidentiality and Sensitive Information form; |
|  | Appendix 6 Basic Information for Certified Customers. |
| SCM |  | Factory plan (required for large manufacturing, transportation and warehousing, and sales industry organizations, indicating vulnerabilities of relevant sites within the physical convenience of the client organization, proximity to assets, proximity to roads/rivers and other access points, etc.) |
|  | Identified security threats and risk evaluation results related to the scope of the organization's supply chain security system; |
|  | List of national and industry applicable laws, regulations and mandatory standards related to supply chain security. |
| INS |  | The latest corporate credit report or audit opinion; Among them, the enterprise credit report shall be issued by the credit information center of the People's Bank of China or the enterprise credit report inquiry network under its jurisdiction; The audit opinion should be issued by a third party financial/audit institution; |
|  | Statement of honesty and law-abiding, no major quality, safety and environmental accidents in the past 1 year; |
|  | A list of laws, regulations and other requirements applicable to its integrity management system; |
| AMS |  | Strategic Asset Management Program (SAMP); |
|  | A list of key asset classes (this may not be provided separately if it is already reflected in the strategic asset management plan); |
|  | List of applicable laws and regulations. |
| Apply for certification certificate transfer organization supplementary information |  | The certification certificates obtained already. |
|  | The audit report of the last audit (initial audit/surveillance/recertification), the audit non-conformity report, the corrective actions taken by the nonconformity rectification and corrective actions validity verification materials, the transfer CB statement, and the transfer certificate information form |
|  | Complaints received and actions taken (when exist); |
|  | Any commitment or agreement with the regulatory authorities regarding compliance |
| Remark：   1. Please click before the information provided, check “” 2. When scope extension application, it is necessary to provide a supporting document that is added or changed due to extension; 3. The above documents and information are provided as attachments to this application (copies will be OK, but they must be clear). | | |

**Appendix 2 Management system certification application (OHSMS applicable)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1.Whether your company has been suing or insurance claims for any occupational health and safety incidents or accidents in the past 5 years (if any, please elaborate):  No  Yes, please briefly describe:(may be on a separate sheet) | | | | | | | | |
|  | | | | | | | | |
| 1. Whether your company has experienced employee injury, poisoning, occupational disease or accident in the past year (if any, please indicate the hazard level of the incident or accident and the number of employees involved):   No  Yes, please briefly describe:(may be on a separate sheet) | | | | | | | | |
|  | | | | | | | | |
| 1. Please indicate the occupational health and safety hazard that may be involved in your company's management system coverage activities: | | | | | | | | |
| Related | | Hazard | | Related | | | Hazard | |
|  | | Asbestos related jobs | |  | | | Working at height | |
|  | | explosives | |  | | | Homework near the vehicle | |
|  | | Work related to flammable materials, storage of flammable materials | |  | | | Food production for other parties | |
|  | | Transportation of dangerous goods | |  | | | Related work involving compressed air | |
|  | | Diving operation | |  | | | Homework in a limited space | |
|  | | Use of materials at extreme temperatures | |  | | | Work with pressure system | |
|  | | Gas-related work | |  | | | Lead and other heavy metals used in the work | |
|  | | Waterside operation (water risk) | |  | | | Work in a smoke/gas/dust environment | |
|  | | Gas-related work | |  | | | Work with chemical hazards | |
|  | | Work related to ionizing radiation | |  | | | Use of work equipment (PUWER) | |
|  | | Use of lifting device and lifting operation | |  | | | Other hazards involved in the work (electricity, noise, use of personal protective equipment, manual operation, etc.) | |
|  | | Related work involving biological hazards | |  | | | other | |
| 1. Do you use, generate, store, dispose of or dispose of hazardous materials? | | | | | No  Yes,Please fill in as follows: (additional pages can be attached) | | | |
| No. | Name of hazardous materials | | Use | | | Hazardous characteristics | | Note |
| 1 |  | |  | | |  | |  |
| 2 |  | |  | | |  | |  |
| 3 |  | |  | | |  | |  |
| 4 |  | |  | | |  | |  |
| Remark：  a、The hazardous characteristics of hazardous materials refer to: flammable, explosive, toxic, corrosive, radioactive, infectious, etc.  b、According to the characteristics of the organization's production and operation activities, to identifiy which hazardous materials are used in the production and operation process, and fills in the requirements in the above table. | | | | | | | | |
| 5.Applicable laws and regulations and other requirements | | | | | | | | |
| Safety Production License (if applicable)  Safety evaluation report (if applicable)  Other： | | | | | | | | |

**Appendix 3 Management System Covered Branches (include Multiple-sites or Temporary-site) Registration Form(Additional pages are available)**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of auditee (seal )** | |  | | | | | | | |
| **Branches(including multiple-site)** | **Registered address** | | **Actual business address** | **Property of place** | **Corresponding scope of certification** | **Total number of staff** | **Sample situation** | **Shifts** | **Sub-certificate** |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |
|  |  | |  | Fixed sites  Temporary sites |  |  |  | Yes  No | Yes  No |

**Appendix 4 List of Building Construction Organization Projects in Progress (EC9000 applicable)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of auditee(seal ):** | |  | | | | | | | **Fill in date** | |  | |
| **No.** | **Temporary site**  **(Project) Name** | | **Nature of temporary site (type of work) Note 4** | **Current progress**  **(under construction)** | **Implementing Department**  **(Project Department)** | **Distance of implementation site from Headquarters** | **Start date** | **End date** | | **Total number of employees** | | **Sampling status**  **(completed by the CB)** |
| 1 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 2 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 3 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 4 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 5 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 6 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 7 |  | |  |  |  |  |  |  | |  | | Yes  No |
| 8 |  | |  |  |  |  |  |  | |  | | Yes  No |

**Remark：**

1. **Engineering organizations need to be filled in and need be audited on-site. Characteristics of engineering-type organizations: a relatively fixed site for a period of time.**
2. **The number of people at temporary sites includes the number of the aduitee’s employees working at temporary sites and the number of subcontractors' employees working at temporary sites.**
3. **Work in progress includes work to be in progress at the time of audit.**
4. **Type of project: housing project, bridge project, water conservancy project, municipal project, etc. (need to be described according to the scope of the qualification of the Ministry of Housing and Construction)**

**Appendix 5 Confidential and Sensitive Information Declaration Form**

|  |  |  |  |
| --- | --- | --- | --- |
| **Organization’s name (seal)** | |  | |
| **No.** | **Confidential and sensitive information assets and or areas** | | **Is the certification body accessible and the requirements for access** |
| 1 |  | |  |
| 2 |  | |  |
| 3 |  | |  |
| 4 |  | |  |
| 5 |  | |  |
| 6 |  | |  |
| 7 |  | |  |
| 8 |  | |  |
| 9 |  | |  |
| 10 |  | |  |
| 11 |  | |  |

**Instructions**：

1. If the relevant information assets cannot be accessed due to the organization's permission or failure to meet applicable requirements, it may result in termination of the audit, reduction of the scope of the audit and certification, and other results.

2、If the organization does not prohibit access to a certain information asset in advance, or fails to inform about the requirements that should be met, during the certification process, it is found that our company does not have the qualifications and conditions to access the information asset, our company will inform the organization, this situation may lead to the termination of the audit , Reduce the scope of audit and certification and other results.

3、Access requirements: legal requirements, requirements of related parties, requirements of the organization itself

**Appendix 6 Basic Information of Certified Customers(ISMS applicable)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Organization’s name(seal):** | | | | |  | | | | | | | | |
| 1 | Amount of users | |  | | | | | Number of IT platforms (infrastructure and application systems): | | | | |  |
| 2 | Number of PCs | |  | | | | | Number of portable computers | | | | |  |
| 3 | Server type (statistics classified by function) | | | | | | | | | |  | | |
| 4 | Number of application developers | | | | |  | | | | Number of operation and maintenance personnel | |  | |
|  | The number of people in the same job in the same business | | | | | | | | | |  | | |
| 5 | Application of Network and Cryptographic Technology | | | | | | | | | | | | |
|  |  | External and/or internal connections with encryption, digital signature and/or PKI requirements; | | | | | | | | | | | |
|  |  | Have external and/or internal connections that use standard encryption facilities without digital signatures and PKI requirements; | | | | | | | | | | | |
|  |  | There are no external and/or internal connections required by encryption, digital signatures, and PKI. | | | | | | | | | | | |
| 6 | The certification preparation status of the client organization (for example: the applied management system has been certified by a third-party organization) | | | | | | | | | | | | |
|  |  | No | | | | | | | | | | | |
|  |  | Yes, the certification body: | | | | |  | | | | | | |
| 7 | The maturity of the client organization's management system (for example: other management systems have passed the certification of the same certification body) | | | | | | | | | | | | |
|  |  | No | | | | | | | | | | | |
|  |  | Yes, the certification body: | |  | | | | | Management system | | | | |

**Appendix 7 Cosmetic Quality Management System information(ISO22716/GMPC applicable)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Organization’s name(seal):** | |  | | |
| Specific product | Implementation of standards（Click ■ to select） | | Administrative License | Annual production |
| National Standards  Industry Standards  enterprise  Customer Requirements | | Cosmetic production license  Hygiene permit |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
|  |  | |  |  |
| Please describe the specific production process of the product scope of the certification (should be described separately according to the product category, the process can be noted), and the other drawings | | | Product use field | Raw material |
|  | | |  |  |
|  | | |  |  |
|  | | |  |  |
|  | | |  |  |
| Main production equipment |  | | | |
| Main inspection equipment |  | | | |
| Product test report |  | | | |

**Appendix 8 Enterprise *Parts and Services" Information Questionnaire* (applicable to MD)**

**If your company's products are not finished medical devices or other service activities, please complete the following questionnaire.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Client Name** |  | | |
| **Scope of management system to be certified** |  | | |
| **Name of product or service activity** |  | | |
| **Intended use of the company's ‘parts and services’ (end products or service recipients)** |  | | |
| **Content of the survey** | | **Yes or No** | **Remark** |
| Is the product a nearly finished and assembled medical device? (i.e., it is intended to be used for a medical purpose and only needs packaging and/or labeling) | | Yes  No |  |
| Is the product intended to be a component/part of a medical device? | | Yes  No |  |
| Is the organization contracted to carry out any activities that are regulated by a medical device regulation (e.g., relabeling, remanufacturing of other medical devices)? | | Yes  No |  |
| Is the product supplied sterile? | | Yes  No |  |
| Does the product contain software developed by the client organization or a supplier? | | Yes  No |  |
| Is “Design and Development” in the scope of the ISO 13485 certification (e.g., when public law permits exclusion of design and development which is the case very often for low-risk medical devices)? | | Yes  No |  |
| Is the product (Raw Materials, Parts, Components, Subassemblies, Maintenance Services, or Other Services) intended to support associated medical devices? | | Yes  No |  |
| **Disclaimer: We confirm that the information provided above is true.** | | | |

**Appendix 9 List of products of the organization applying for certification (FSMS/HACCP applicable)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Application Organization’s name(seal):** | |  | | | | |
| **Product name** | **Product implementation standard name and code** | | **Production site/workshop** | **Production (tons)** | **Output value (ten thousand yuan)** | **\*Product category (for products within the scope of food production license)** |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |
|  |  | |  |  |  |  |

**\*Product Category Fill in the food and food additive category on the license**

**Appendix 10 Information on the use of food additives (FSMS/HACCP applicable)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name of Applicant organization (seal)** | |  | | | | |
| The products of the company do not use any food additives in the production and processing engineering.  The company's products use the following food additives in the production and processing engineering: | | | | | | |
| **No.** | **Food additive name** | **\*Food additive category (Compound additive not filled)** | **Use**  **(Compound additive fill)** | **Applicable product** | **Actual usage** | **Defined limit standard** |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |
| 11 |  |  |  |  |  |  |
| 12 |  |  |  |  |  |  |

**\*The food additive category means the food additive category specified in the GB 2760 standard**

**Annex 1: Self-Declaration of the Applicant organization (FSMS/HACCP applicable)**

|  |  |
| --- | --- |
| 1、Our products are produced according to the domestic/export product standards: | |
|  | |
| 1. The products of the enterprise have been sent to the relevant inspection institutions for inspection, and all the indicators have passed (see the copy of the inspection report); | |
| 1. Whether additives are used in the formula of the products produced by this enterprise   Not used  For use, please fill in *Instructions on the Use of Appendix 10 Food Additives*  4、Within one year, the company has not violated the relevant laws and regulations of China and the importing country (region) of food safety and hygiene accidents;  5、Within five years, the enterprise has not violated serious food safety and hygiene accidents or failed to take effective measures to deal with major complaints from relevant parties, and falsely reported or concealed the information required for certification and was revoked by the certification body;  6、The company voluntarily undertakes to establish and implement a management system on the basis of complying with national laws and regulations, the corresponding national or industry/local standards and certification norms, to ensure that the products provided to consumers meet the quality and health and safety requirements.  Hereby declare！ | |
| Representative |  |
|  |  |
| Seal |  |
|  |  |
| Date |  |
|  |  |