



# مركز الإمارات العالمي للاعتماد

# **Emirates International Accreditation Centre**

# متطلبات اعتماد جهات منح الشهادات لنظم الإدارة

# Accreditation requirements for Certification Bodies of Management Systems Certifications

EIAC-RQ-CB-001

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|           |                  | other schemes were also added.                                     |            |  |  |
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|           |                  | Quality Management Systems (ISO 13485)                             |            |  |  |



## Accreditation requirements for Certification Bodies of Management Systems Certifications EIAC-RQ-CB-001, Issue 2, Rev. 02, 25 December 2024



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### 1 Scope

- 1.1 This document is applicable on management systems certification programs/schemes of the Emirates International Accreditation Centre (EIAC).
- 1.2 This document is applicable on the certification bodies that are certifying the management systems including but not limited to the ISO 9001, ISO 14001, ISO 22000, ISO 45001, ISO 27001, ISO 37001, ISO 50001, ISO 22301, ISO 41001, ISO 37301, ISO 13485, HACCP and DOH/SD/ADHICS/0.9 Abu Dhabi Healthcare information and cyber security standard.

#### 2 Definitions

### 2.1 Certification Body (CB)

For the purpose of this accreditation, a certification body is an independent & impartial third-party body, possessing the necessary competence and reliability and operates in accordance with main standard ISO/IEC 17021-1 and associated technical specifications to perform management system(s) certifications.

#### 2.2 Key Activities

Policy formulation; Process and/or procedure development; Initial approval of auditing personnel, or control of their training; On-going monitoring of auditing personnel; Application review; Assignment of auditing personnel; Control of surveillance or recertification audits; Final report review or certification decision or approval, certificate issuing.

### 2.3 Branch Office of CB

The other fixed office location(s), regional office(s), franchisee (s), subcontracted office(s) are referred to as branch office of Certification body in this document.

#### 2.4 Other Certification Office of CB

The branch office of certification body from where it intends to issue EIAC accredited certificates and intends to write the address of this branch office on the certificates. The other certification office must be under direct legal control of the certification body.

### 2.5 Shall

The term "shall" is used throughout this document to indicate those provisions which, reflect the requirements are mandatory.

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### 3 General requirements

- 3.1 The Certification Body (CB) shall be a legally licensed entity, and all employees of the certification body shall have legally valid document/permission to work for the certification body.
- 3.2 The Certification Body (CB) applying for accreditation shall have a management system in compliance with ISO/IEC 17021-1. The CB shall also follow the relevant technical specifications/standards as applicable. Some of the technical specifications/standards that shall be followed are given below:
  - 3.2.1 For ISO 14001: Compliance with ISO/IEC TS 17021-2
  - 3.2.2 For ISO 9001: Compliance with ISO/IEC TS 17021-3
  - 3.2.3 For ISO 22000: Compliance with ISO TS 22003
  - 3.2.4 For ISO 27001: Compliance with the ISO/IEC 27006
  - 3.2.5 For ISO 37001: Compliance with ISO TS 17021-9
  - 3.2.6 For ISO 45001: Compliance with ISO TS 17021-10
  - 3.2.7 For ISO 22301: Compliance with ISO/IEC TS 17021-6
  - 3.2.8 For ISO 50001: Compliance with ISO 50003
  - 3.2.9 For ISO 41001: Compliance with ISO/IEC TS 17021-11
  - 3.2.10 For ISO 37301: Compliance with ISO/IEC TS 17021-13
- 3.3 The CB shall fulfill the specific mandatory criteria defined in relevant International Accreditation Forum (IAF) MD documents. It should also consider the guidance defined in the relevant IAF & Pacific Accreditation Cooperation (PAC) and Arab Accreditation Cooperation (ARAC) documents published time to time (These documents are available on websites of respective accreditation cooperations).
- The CB shall have a system to conduct two-stage initial audits on their clients and at least part of stage 1 audit to be carried out at clients' premises.
- 3.5 The CB shall only provide exclusions from the certification scope to its clients where such exclusions are allowed within the scope of respective certification criteria (international standard). The exclusions in any way shall not undermine the effectiveness of certification and shall not cause any confusion among clients of certified entities and interested parties and mislead them about certified scope.
- 3.6 The CB shall have agreements & arrangements with all clients so that any of the CB's audit can be witnessed by the EIAC assessors.

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- 3.7 The CB shall also have agreements & arrangements with all clients that at any time during the certification cycle EIAC assessors can visit the client premises to verify certain certification requirements. The CB representative(s) may accompany the EIAC assessors.
- 3.8 Management system documents including quality manual and procedures of CBs shall be available in English language. Quality records including internal audit, management review, and records related to safeguarding impartiality shall also be in English language.
- 3.9 The CB shall employ suitable and qualified technical and administrative staff. As availability of minimum resources, the CB is required to have at least one permanently employed application/contract reviewer, one qualified auditor and one qualified certification decision maker for the certification scheme applied for accreditation/accredited certification scheme.
- 3.10 The certification body shall define the competence criteria and evaluation process for key positions related to each certification scheme. The CB shall formally approve and authorize application/contract reviewer(s), auditor(s) and certification decision maker(s) for each applicable certification scheme and relevant technical area/codes/clusters.
- 3.11 The CB shall have legally valid contract with all its empaneled auditors and experts with clearly stipulated terms & conditions and remuneration package.
- 3.12 At the time of applying for accreditation, the applicant CB must have met the following conditions:
  - a) Granted at least one certification for the scheme applied for accreditation or the CB has two applicants for which they have completed at least stage 1 audit for one client.
  - b) Conducted at least one internal audit and one management review.
  - c) Conducted at least one comprehensive review of risks to impartiality/potential conflict of interests, with consultation/participation of balanced interested parties.
- 3.13 Accredited certification bodies are required to submit accumulated data reports containing certification details under EIAC accreditation scheme(s) and up to date lists of authorized auditors for EIAC accreditation scheme(s) on prescribed formats on 10 January, 10 April, 10 July and 10 October every year.
- 3.14 Codes grouping for witness audits for ISO 22000 and HACCP certification audits are given in EIAC-RQ-CB-002 and codes grouping for witness audits for ISO 27001 certification audits are given in EIAC-RQ-CB-003.
- 3.15 EIAC uses IAF Informative Document for QMS and EMS Scopes of Accreditation IAF ID 1 as basis for defining accreditation scope for ISO 9001, ISO 14001, ISO 45001, ISO 27001, ISO 50001 and ISO 22301.

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- 3.16 The CB is obliged to send the following documents to EIAC lead assessor/assessment team member before each audit to be witnessed;
  - a) CV(s) of auditor(s) including confirmation that auditor(s) and technical experts (if any) are qualified for the relevant technical area.
  - b) Man days calculation/estimation (justification for calculation of the audit time).
  - c) Previous audit report (if applicable),
  - d) Audit plan for the audit to be witnessed.
  - e) Audit report of the witnessed audits (to be sent after the witness audit once CB's audit team has prepared the report)
- 3.17 When the CB is found to provide certification to any standard used as a basis for accreditation of conformity assessment bodies such as ISO 17025, ISO 15189, ISO 17020 etc, the EIAC shall initiate the process for suspension of accreditation of such CB.
- 3.18 Where there is evidence of fraudulent behavior, or the certification body intentionally provides false information or conceals information, the EIAC shall initiate its process for withdrawal of accreditation.
- 3.19 The certification body shall not certify any illegal entity and illegal activity/scope. The certification body shall maintain the record of legal license (the name/title of such document may vary in various jurisdictions) of certified entity.

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### 4 Time & duration requirements for office assessment & witness audits.

The time required for assessment is based on the following main elements which are covered during assessment:

- Number of schemes applied for accreditation
- · Head office assessment.
- Assessment of all locations where key activities take place.
- Witness audits for different scopes of certification

#### 4.1 Initial Assessment

#### 4.1.1 Office assessment

- 4.1.1.1 This is the assessment conducted at CB's office. Total number of required man days depends upon the applied scope. Minimum one-man day is required if the CB operates all key activities from the applicant office only and the applied scope of accreditation is for one standard, such as ISO 9001 for limited code(s) from one technical cluster. In case CB has applied accreditation for more standards & codes then man-days may be increased for office assessment.
- 4.1.1.2 All critical locations shall be assessed during initial assessment.
  - All branches where key activities are carried out with respect to EIAC applied scope shall be assessed at the time of initial assessment.
- 4.1.1.3 All other branches, where any key activity is not carried out and CB wants to include subject branches in EIAC accreditation scope document, shall be assessed at the time of initial assessment.

#### 4.1.2 Witness Audits

- 4.1.2.1 Minimum two audits shall be witnessed to grant accreditation for any applied standard. For witness audits, stage 1, stage 2 certification audits (and recertification audits) are preferred; however, surveillance audits can also be witnessed.
- 4.1.2.2 Audits shall be witnessed as per the IAF policies defined in IAF MD 16, IAF MD 17, IAF MD 8 and this document.

  Note: Witness requirements for ISO 22000/HACCP certifications and ISO 27001 certifications are defined in EIAC-RQ-CB-002, and EIAC-RQ-CB-003 respectively.
- 4.1.2.3 The IAF codes for ISO 9001, ISO 14001, ISO 45001 & ISO 13485 certifications and other standards are categorized in technical clusters and critical codes scope and are given in annexes of this requirement document.
- 4.1.2.4 Total number of witness audits can be reduced if the head office of the CB has directly applied for EIAC accreditation and holds accreditation(s) for the same scope(s) from any other MLA signatory accreditation body

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(ies). In this case, the CB shall provide access to assessment reports issued by other accreditation body (ies). This reduction is not applicable to branch offices directly seeking EIAC accreditation unless the branch office is directly accredited for the same scope(s) from any other MLA signatory accreditation body (ies). In this case witness audits for surveillance may also be reduced.

- 4.1.2.5 The IAF codes for ISO 50001 certifications are categorized in code groups as mentioned in Annex-4.

  If a CB applies for accreditation for all IAF codes for ISO 50001 certifications, then at least one certification audit of each of the code groups shall be witnessed for the corresponding scope during accreditation assessment of certification bodies (Annex-4).
- 4.1.2.6 The IAF codes for ISO 22301 certifications are categorized in code groups as mentioned in Annex-5.

  If a CB applies for accreditation for all IAF codes for ISO 22301 certifications, then at least one certification audit of each of the code groups shall be witnessed for the corresponding scope during accreditation assessment of certification bodies (Annex-5).
- 4.1.2.7 The scope for ISO 37001 certifications is categorized in technical cluster groups as mentioned in Annex-6. If a CB applies for accreditation for all technical clusters, then at least one certification audit from each of the technical cluster groups shall be witnessed for the corresponding scope during accreditation assessment of certification bodies.
- 4.1.2.8 The scope for ISO 41001 certifications is categorized in technical cluster groups as mentioned in Annex-7. If a CB applies for accreditation for all technical clusters, then at least one certification audit from each of the technical cluster groups shall be witnessed for the corresponding scope during accreditation assessment of certification bodies.
- 4.1.2.9 The scope for ISO 37301 certifications is categorized in technical cluster groups as mentioned in Annex-8. If a CB applies for accreditation for all technical clusters, then at least one certification audit from each of the technical cluster groups shall be witnessed for the corresponding scope during accreditation assessment of certification bodies.
- 4.1.2.10 The scope for ISO 13485 certifications is categorized in main technical areas as mentioned in Annex-9 (Table 1.1 to 1.7). If a CB applies for accreditation for all main technical areas, then at least one certification audit from each of the main technical areas from each table (table 1.1 to 1.7) shall be witnessed for the corresponding scope during accreditation assessment of certification bodies.

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#### 4.2 Surveillance

- 4.2.1 During the accreditation cycle, the EIAC should conduct surveillance every year. An accreditation cycle shall begin at or after the date of the decision for granting the initial accreditation or decision after reassessment. The surveillance activities may include assessment, review of CB's data reports and feedback from clients/market.
- 4.2.2 For each accredited standard (such as ISO 9001, ISO 14001, ISO 45001), separate witness audit should be conducted. Combined audit of two or more standards can also be witnessed. The required number of audits to be witnessed is decided as per the IAF policies defined in IAF MD 17, IAF MD 16 and IAF MD 8. Base line for required witness audits is minimum one audit should be witnessed.
- 4.2.3 The number of man days for office assessment & witness audit can be increased by considering the following factors:
  - The number of clients certified by the CB with EIAC accreditation,
  - The number of auditors employed/empaneled by the CB,
  - Feedback from the market,
  - Complaints received and inputs from any office assessment.
- 4.2.4 EIAC may select any auditor to witness from CB's list of approved auditors.
- 4.2.5 EIAC may select any certified company (client) with EIAC accreditation for the witness audit.
- 4.2.6 The witness audits should be conducted by various approved auditors for various scopes. EIAC witnesses the maximum number of auditors and all scope groups within the accreditation cycle. Witness assessments should avoid repeated witnessing of the same CAB client organization.

#### 4.3 Reassessment

- 4.3.1 The reassessment is similar to initial assessment, however, the information gathered from assessments performed over the accreditation cycle is considered.
- 4.3.2 It is expected that total number of man-days would be less than the initial assessment and more than any surveillance assessment.

#### 4.4 Scope Extension

- 4.4.1 For scope extension, both office assessment & witness audits may be applicable.
- 4.4.2 The required number of witness audits depends upon the applied scope.

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### 4.5 Extraordinary Assessments

- 4.5.1 The EIAC may conduct additional special surveillance visits (extraordinary assessments) as a result of complaints or changes, or other matters that may affect the ability of the certification body to fulfil requirements for accreditation.
- 4.5.2 During surveillance assessment, EIAC may decide to verify the authenticity of certification process by conducting short visits to some of the selected certified clients. The EIAC assessor will visit the certified company and verify the implementation of the system(s) by reviewing some of quality documentation & records and by meeting with the certified companies' management. The CB representative may accompany the EIAC assessor during such visit(s).

#### 4.6 Multi Location Certification Bodies

- 4.6.1 The certification bodies may operate from various geographical locations. All such locations where one or more key activities are conducted or controlled are subject of EIAC assessment.
- 4.6.2 The CB shall formally apply and seek approval of EIAC for inclusion of a branch office and or new geographical location for certification in EIAC scope of accreditation.
- 4.6.3 If a CB is operating in one country (country A) and intends to offer EIAC accredited certifications in another country (country B) by establishing a branch office in country B. Then EIAC will assess the branch office in country B and after successful assessment & EIAC's scope extension decision, subject branch office shall be included in scope of accreditation.
- 4.6.4 If a CB is operating in one country (country A) and intends to offer EIAC accredited certifications through branches in other cities of the same country. Then same principle applies as mentioned in above clause.
- 4.6.5 At initial assessment EIAC will visit all such branches.
- 4.6.6 At the surveillance assessment EIAC will select the sample of branches.
- 4.6.7 If a CB has its head office in one country and provides EIAC accredited services to various other countries by managing all key activities from head office. The CB shall apply and seek approval of EIAC before providing certification in any other country/economy. Then EIAC may decide to witness the audit (s) in those countries as applicable. After EIAC's scope extension decision, subject country (ies) shall be included in scope of accreditation.
- 4.6.8 If a CB intends to issue certificates from its any "other certification office" and intends to write the address of that certification office on the certificate, the CB shall formally apply and seek approval of EIAC for inclusion of "other certification office" in the scope of accreditation. The other certification office must be under direct legal

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control of the certification body. The certification body shall be an owner/shareholder of the "other certification office".

- 4.6.9 The EIAC shall conduct assessment at that "other certification office" and after successful assessment & EIAC's scope extension decision, subject "other certification office" shall be included in the scope of accreditation.
- 4.6.10 The EIAC follows cross-frontier accreditation policy while accrediting foreign CBs.

### 5 EIAC accredited certificates

- 5.1 The accredited certification bodies are entitled to issue certificates bearing EIAC accreditation symbol for accredited scope only.
- 5.2 Before using EIAC accreditation symbol or any reference to EIAC accreditation symbol, the accredited certification bodies are required to take formal approval from EIAC for the use of EIAC accreditation symbol or any reference regarding EIAC accreditation. [Ref: Doc. EIAC-RQ-GEN-002]
- 5.3 The certificate must contain the full name and full address of head office of certification body. If "other certification office" of CB is included in the EIAC's scope of accreditation then address of "other certification office" can be written/printed on the certificate.
- 5.4 The certificate must contain the full name and full address of a certified client.
- 5.5 The certificate must contain the scope of certification along with relevant IAF and NACE code(s) as mentioned on the accreditation certificate and scope of the CB, as applicable.
- As specified in the IAF Resolutions 2015-14 and 2016-17, CBs shall not issue any non-accredited certificates in the scopes for which they hold EIAC accreditation and, further to this, all certificates covered by accreditation must include the EIAC accreditation symbol or reference to EIAC Accreditation.
- 5.7 Non-accredited certificates can be issued for new scope areas/new certification schemes where the CB is working towards accreditation. Once the accreditation is granted, the CB is required to transfer the previously issued non-accredited certificates to accredited ones within 90 days. These transfers may require the CB to carry out a review/additional audit of all such certifications.

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### 6 Suspension of Accreditation

- 6.1 If the accreditation of CB is suspended. The CB is required to take corrective action and remove the reason of accreditation within three months of suspension.
- 6.2 If CB is not able to implement corrective action or remove the reasons of suspension within three months, then it can request to EIAC for extension in suspension duration. EIAC may extend the suspension to six months.
- 6.3 In case the CB does not implement the corrective action or remove the reasons of suspension within six months, the accreditation should be withdrawn.
- 6.4 EIAC may require conducting follow-up assessment to verify the corrective actions taken by the CB before lifting the suspension.

### 7 Scope Reduction or Withdrawal of Accreditation

- 7.1 If the scope of accreditation of CB has been reduced either voluntarily by CB or by EIAC, the accredited CB is required to recall all EIAC accredited certificates related to the reduced scope within stipulated time by EIAC.
- 7.2 If the accreditation of CB has been withdrawn either voluntarily by CB or by EIAC, the accredited CB is required to recall all EIAC accredited certificates within stipulated time by EIAC.

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### 8 Annex no. 1: Scope for ISO 9001 Quality Management Systems Certification

| Technical    | IAF  | NACE Code                              | Description                                       | Critical |  |
|--------------|------|--|---|----------|--|
| Cluster      | Code | (Rev. 02)                              |   | Code(s)  |  |
| Food         | 1    | 01, 02, 03                             | Agriculture, forestry and fishing                 | 3        |  |
|              | 3    | 10, 11, 12                             | Food products, beverages and tobacco              |          |  |
|              | 30   | 55,56                                  | Hotels and restaurants                            |          |  |
| Mechanical   | 17   | 24 except 24.46, 25 except 25.4, 33.11 | Basic metals and fabricated metal products        | 22 or 20 |  |
|              | 18   | 25.4, 28, 30.4, 33.12, 33.2            | Machinery and equipment                           |          |  |
|              | 19   | 26, 27, 33.13, 33.14, 95.1             | Electrical and Optical Equipment                  |          |  |
|              | 20   | 30.1, 33.15                            | Shipbuilding                                      |          |  |
|              | 22   | 29, 30.2, 30.9, 33.17                  | Other transport equipment                         |          |  |
| Paper        | 7    | 17                                     | Limited to "Paper products"                       | 9        |  |
|              | 8    | 58.1, 59.2                             | Publishing companies                              |          |  |
|              | 9    | 18                                     | Printing companies                                |          |  |
| Minerals     | 2    | 05, 06, 07, 08, 09                     | Mining and quarrying                              | 2 or 15  |  |
|              | 15   | 23, except 23.5 & 23.6                 | Non-metallic mineral products                     |          |  |
|              | 16   | 23.5, 23.6                             | Concrete, cement, lime, Plaster etc               |          |  |
| Construction | 28   | 41,42,43                               | Construction                                      | 28       |  |
| 34           |      | 71 , 72 , 74 except 74.2 & 74.3        | Engineering services                              |          |  |
| Goods        | 4    | 13, 14                                 | Textiles and textile products                     | 5 or 14  |  |
| Production   | 5    | 15                                     | Leather and leather products                      |          |  |
|              | 6    | 16                                     | Wood and wood products                            |          |  |
|              | 14   | 22                                     | Rubber and plastic products                       |          |  |
|              | 23   | 31,32,33.19                            | Manufacturing not elsewhere classified            |          |  |
| Chemicals    | 7    | 17                                     | Limited to "Pulp and paper manufacturing"         | 12       |  |
|              | 10   | 19                                     | Manufacture of coke and refined petroleum product |          |  |
|              | 12   | 20                                     | Chemicals, Chemicals Products and Fibers          |          |  |

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| Technical   | IAF  | NACE Code                         | Description                              | Critical |
|-------------|------|-----------------------------------|--|----------|
| Cluster     | Code | (Rev. 02)                         |  | Code(s   |
|             |      |                                   |  | )        |
| Supply      | 25   | 35.1                              | Electricity Supply                       | 26       |
|             | 26   | 35.2                              | Gas supply                               |          |
|             | 27   | 35.3, 36                          | Water supply                             |          |
| Transport & | 24   | 38.3                              | Recycling                                | 24       |
| Waste       | 31   | 49,50,51,52,53,61                 | Transport, storage and communication     |          |
| management  | 39   | 37, 38.1, 38.2, 39, 59.1, 60      | Other social services                    |          |
|             |      | , 63.9 , 79 , 90 , 91 , 92 , 93 , |  |          |
|             |      | 94,96                             |  |          |
| Services    | 29   | 45, 46, 47, 95.2                  | Wholesale and Retail Trade; Repair of    | 37 or 33 |
|             |      |                                   | motor vehicles, motorcycles and personal |          |
|             |      |                                   | and household goods                      |          |
|             | 32   | 64,65,66,68,77                    | Financial Intermediation, real estate,   |          |
|             |      |                                   | renting                                  |          |
|             | 33   | 58.2,62,63.1                      | Information technology                   |          |
|             | 35   | 69,70,73,74.2,74.3,78,            | Other services                           |          |
|             |      | 80,81,82                          |  |          |
|             | 36   | 84                                | Public administration                    |          |
|             | 37   | 85                                | Education                                |          |
| Nuclear     | 11   | 24.46                             | Nuclear fuel                             | 11       |
| Pharmaceuti | 13   | 21                                | Pharmaceuticals                          | 13       |
| cal         |      |                                   |  |          |
| Aerospace   | 21   | 30.3,33.16                        | Aerospace                                | 21       |
| Health      | 38   | 75,86,87,88                       | Health & social work                     | 38       |

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### 9 Annex no. 2: Scope for ISO 14001 Environmental Management Systems Certification

| Technical    | IAF      | NACE Code                   | Description                                       | Critical         |  |
|--------------|----------|-----------------------------|---|------------------|--|
| Cluster      | Code     | (Rev. 02)                   |   | Code(s)          |  |
| Agriculture, | 1        | 01, 02, 03                  | Agriculture, forestry and fishing                 | 1                |  |
| Forestry and |          |                             |   |                  |  |
| Fishing      |          |                             |   |                  |  |
| Food         | 3        | 10, 11, 12                  | Food products, beverages and tobacco              | 3                |  |
|              | 30       | 55,56                       | Hotels and restaurants                            |                  |  |
| Mechanical   | 17       | 25 except 25.4, 33.11       | Limited to "Fabricated metal products"            | 20 or 21         |  |
|              | 18       | 25.4, 28, 30.4, 33.12, 33.2 | Machinery and equipment                           |                  |  |
|              | 19       | 26, 27, 33.13, 33.14, 95.1  | Electrical and Optical Equipment                  |                  |  |
|              | 20       | 30.1, 33.15                 | Shipbuilding                                      |                  |  |
|              | 21       | 30.3, 33.16                 | Aerospace   |                  |  |
|              | 22       | 29, 30.2, 30.9, 33.17       | Other transport equipment                         |                  |  |
| Paper        | 7        | 17                          | Limited to "Paper products"                       | 9                |  |
|              | 8        | 58.1,59.2                   | Publishing companies                              |                  |  |
|              | 9        | 18                          | Printing companies                                |                  |  |
| Construction | 28       | 41,42,43                    | Construction                                      | 28               |  |
|              | 34       | 71,72,74 except 74.2 & 74.3 | Engineering services                              |                  |  |
| Goods        | 4        | 13, 14                      | Textiles and textile products                     | 4 and 5          |  |
| Production   | 5        | 15                          | Leather and leather products                      |                  |  |
|              | 6        | 16                          | Wood and wood products                            |                  |  |
|              | 23       | 31,32,33.19                 | Manufacturing not elsewhere classified            |                  |  |
| Technical    | IAF Code | NACE Code                   | Description                                       | Critical         |  |
| Cluster      |          | (Rev. 02)                   |   | Code(s)          |  |
| Chemicals    | 7        | 17                          | Limited to "Pulp and paper manufacturing"         | 7 and 10         |  |
|              | 10       | 19                          | Manufacture of coke and refined petroleum product | and 12 and<br>13 |  |
|              | 12       | 20                          | Chemicals, Chemicals Products and Fibers          |                  |  |
|              | 13       | 21                          | Pharmaceuticals                                   |                  |  |

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| Technical Cluster | IAF  | NACE Code Description        |  | Critical     |
|-------------------|------|------------------------------|--|--------------|
|                   | Code | (Rev. 02)                    |  | Code(s)      |
| Chemicals         | 14   | 22                           | Rubber and plastic products            | 7 and 10 and |
|                   | 15   | 23, except 23.5 & 23.6       | Non-metallic mineral products          | 12 and 13    |
|                   | 16   | 23.5, 23.6                   | Concrete, cement, lime, Plaster etc    |              |
|                   | 17   | 24 except 24.46              | Limited to "Base metals production"    |              |
| Mining and        | 2    | 05, 06, 07, 08, 09           | Mining and quarrying                   | 2            |
| quarrying         |      |                              |  |              |
| Supply            | 25   | 35.1                         | Electricity Supply                     | 25 or 26     |
|                   | 26   | 35.2                         | Gas supply                             |              |
|                   | 27   | 35.3,36                      | Water supply                           |              |
| Transport & Waste | 24   | 38.3                         | Recycling                              | 24 and 39    |
| management        | 31   | 49,50,51,52,53,61            | Transport, storage and communication   | (limited to  |
|                   | 39   | 37,38.1,38.2,39,59.1,        | Other social services                  | NACE 37,     |
|                   |      | 60,63.9,79,90,91,92          |  | 38.1, 38.2,  |
|                   |      | , 93 , 94 , 96               |  | 39)          |
| Services          | 29   | 45, 46, 47, 95.2             | Wholesale and Retail Trade; Repair of  | 29 or 35 or  |
|                   |      |                              | motor vehicles, motorcycles and        | 36           |
|                   |      |                              | personal and household goods           |              |
|                   | 32   | 64,65,66,68,77               | Financial Intermediation, real estate, |              |
|                   |      |                              | renting                                |              |
|                   | 33   | 58.2,62,63.1                 | Information technology                 |              |
|                   | 35   | 69 , 70 , 73 , 74.2 , 74.3 , | Other services                         |              |
|                   |      | 78,80,81,82                  |  |              |
|                   | 36   | 84                           | Public administration                  |              |
|                   | 37   | 85                           | Education                              |              |
|                   |      |                              |  |              |
| Nuclear           | 11   | 24.46                        | Nuclear fuel                           | 11           |
|                   |      |                              |  |              |
| Health            | 38   | 75,86,87,88                  | Health & social work                   |              |

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# Annex no. 3: Scope for ISO 45001 Occupational health and safety Management Systems Certification

| Technical Cluster    | IAF  | NACE Code  | Description                            | Critical     |
|----------------------|------|--|--|--------------|
|                      | Code | (Rev. 02)  |  | Code(s)      |
| Agriculture,         | 1    | 01, 02, 03   | Agriculture, forestry and fishing      | 1            |
| Forestry and Fishing |      |  |  |              |
| Food                 | 3    | 10, 11, 12   | Food products, beverages and tobacco   | 3            |
|                      | 30   | 55,56  | Hotels and restaurants                 |              |
| Mechanical           | 17   | 25 except 25.4, 33.11                              | Limited to "Fabricated metal products" | 20 or 21     |
|                      | 18   | 25.4, 28, 30.4, 33.12, 33.2                        | Machinery and equipment                |              |
|                      | 19   | 26, 27, 33.13, 33.14, 95.1                         | Electrical and Optical Equipment       |              |
|                      | 20   | 30.1,33.15   | Shipbuilding                           |              |
|                      | 21   | 30.3, 33.16  | Aerospace                              |              |
|                      | 22   | 29 , 30.2 , 30.9 , 33.17 Other transport equipment |  |              |
| Paper                | 7    | 17   | Limited to "Paper products"            | 9            |
|                      | 8    | 58.1,59.2  | Publishing companies                   |              |
|                      | 9    | 18   | Printing companies                     |              |
| Construction         | 28   | 41,42,43   | Construction                           | 28           |
|                      | 34   | 71,72,74 except 74.2 & 74.3                        | Engineering services                   |              |
| Goods Production     | 4    | 13, 14   | Textiles and textile products          | 4 (with      |
|                      | 5    | 15   | Leather and leather products           | tanning) and |
|                      | 6    | 16   | Wood and wood products                 | 5 or 6       |
|                      | 23   | 31,32,33.19  | Manufacturing not elsewhere            |              |
|                      |      |  | classified                             |              |
| Technical Cluster    | IAF  | NACE Code  | Description                            | Critical     |
|                      | Code | (Rev. 02)  |  | Code(s)      |
| Chemicals            | 7    | 17   | Limited to "Pulp and paper             | 7 and 10 and |
|                      |      |  | manufacturing"                         | 12 and 13    |
|                      | 10   | 19   | Manufacture of coke and refined        | and 16 or 17 |
|                      |      |  | petroleum product                      |              |

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| Technical Cluster | IAF  | NACE Code                    | Description                            | Critical       |
|-------------------|------|------------------------------|--|----------------|
|                   | Code | (Rev. 02)                    |  | Code(s)        |
| Chemicals         | 12   | 20                           | Chemicals, Chemicals Products and      | 7 and 10 and   |
|                   |      |                              | Fibers                                 | 12 and 13      |
|                   | 13   | 21                           | Pharmaceuticals                        | and 16 or 17   |
|                   | 14   | 22                           | Rubber and plastic products            |                |
|                   | 15   | 23, except 23.5 & 23.6       | Non-metallic mineral products          |                |
|                   | 16   | 23.5, 23.6                   | Concrete, cement, lime, Plaster etc    |                |
|                   | 17   | 24 except 24.46              | Limited to "Base metals production"    |                |
| Mining and        | 2    | 05, 06, 07, 08, 09           | Mining and quarrying                   | 2              |
| quarrying         |      |                              |  |                |
| Supply            | 25   | 35.1                         | Electricity Supply                     | 25 or 26       |
|                   | 26   | 35.2                         | Gas supply                             |                |
|                   | 27   | 35.3,36                      | Water supply                           |                |
| Transport & Waste | 24   | 38.3 Recycling               |  | 31 (limited to |
| management 31     |      | 49,50,51,52,53,61            | Transport, storage and communication   | dangerous      |
|                   | 39   | 37,38.1,38.2,39,59.1,        | Other social services                  | goods), and    |
|                   |      | 60,63.9,79,90,91,92          |  | 24 or 39       |
|                   |      | , 93 , 94 , 96               |  | (limited to    |
|                   |      |                              |  | NACE 37,       |
|                   |      |                              |  | 38.1, 38.2,    |
|                   |      |                              |  | 39)            |
| Services          | 29   | 45, 46, 47, 95.2             | Wholesale and Retail Trade; Repair of  | 29 or 35 or    |
|                   |      |                              | motor vehicles, motorcycles and        | 36             |
|                   |      |                              | personal and household goods           |                |
|                   | 32   | 64,65,66,68,77               | Financial Intermediation, real estate, |                |
|                   |      |                              | renting                                |                |
|                   | 33   | 58.2,62,63.1                 | Information technology                 |                |
|                   | 35   | 69 , 70 , 73 , 74.2 , 74.3 , | Other services                         |                |
|                   |      | 78,80,81,82                  |  |                |
|                   | 36   | 84                           | Public administration                  |                |
|                   | 37   | 85                           | Education                              |                |
|                   | I .  | I .                          | I .                                    |                |

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| Technical Cluster | IAF<br>Code | NACE Code<br>(Rev. 02) | Description          | Critical<br>Code(s) |
|-------------------|-------------|------------------------|----------------------|---------------------|
| Nuclear           | 11          | 24.46                  | Nuclear fuel         | 11                  |
| Health            | 38          | 75,86,87,88            | Health & social work | 38                  |

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### 11 Annex no. 4: Scope for ISO 50001 Energy Management Systems Certification

| Scope Group         | IAF | Codes   |
|---------------------|-----|---|
|                     |     |   |
| Technical Cluster 1 | 10  | Manufacture of coke and refined petroleum products                    |
|                     | 11  | Nuclear fuels   |
|                     | 14  | Rubber and plastic products   |
|                     | 15  | Non-metallic mineral products   |
|                     | 16  | Concrete, cement, lime, Plaster etc.                                  |
|                     | 17  | Basic metals and fabricated metal products                            |
|                     | 18  | Machinery and equipment   |
|                     | 19  | Electrical and optical equipment                                      |
|                     | 20  | Shipbuilding  |
|                     | 21  | Aerospace   |
|                     | 22  | Other transport equipment   |
|                     | 28  | Construction  |
| Technical Cluster 2 | 1   | Agriculture, fishing  |
|                     | 2   | Mining and quarrying  |
|                     | 3   | Food Products, beverages and Tobacco                                  |
|                     | 4   | Textiles and Textile products   |
|                     | 5   | Leather and Leather products  |
|                     | 6   | Wood and wood products  |
|                     | 7   | Pulp, paper and paper products  |
|                     | 12  | Chemicals, chemical products and fibers                               |
|                     | 13  | Pharmaceuticals   |
|                     | 23  | Manufacturing not elsewhere classified                                |
| Technical Cluster 3 | 24  | Recycling   |
|                     | 25  | Electricity Supply  |
|                     | 26  | Gas supply  |
|                     | 27  | Water supply  |
|                     | 29  | Wholesale and retail trade; Repair of motor vehicles, motorcycles and |
|                     |     | personal and household goods  |
|                     | 33  | Information technology  |
|                     | 34  | Engineering services  |

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| Scope Group         | IAF Codes   |
|---------------------|---|
|                     |   |
| Technical Cluster 4 | 8 Publishing companies                            |
|                     | 9 Printing companies                              |
|                     | 30 Hotels and restaurants                         |
|                     | 31 Transport, Storage and communication           |
|                     | 32 Financial Intermediation, real estate, renting |
|                     | 35 Other services                                 |
|                     | 36 Public administration                          |
|                     | 37 Education                                      |
|                     | 38 Health & social work                           |
|                     | 39 Other social services                          |

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### 12 Annex no. 5: Scope for ISO 22301 Business Continuity Management Systems Certification

| Scope Group         | IAF Codes  |
|---------------------|--|
|                     |  |
| Technical Cluster 1 | 1 Agriculture, fishing   |
|                     | 3 Food Products, beverages and Tobacco                                   |
|                     | 12 Chemicals, chemical products and fibers                               |
|                     | 13 Pharmaceuticals   |
|                     | 30 Hotels and restaurants  |
| Technical Cluster 2 | 4 Textiles and Textile products  |
|                     | 5 Leather and Leather products   |
|                     | 6 Wood and wood products   |
|                     | 7 Pulp, paper and paper products   |
|                     | 8 Publishing companies   |
|                     | 9 Printing companies   |
|                     | 10 Manufacture of coke and refined petroleum product                     |
|                     | 14 Rubber and plastic products   |
|                     | 15 Non-metallic mineral products   |
|                     | 16 Concrete, cement, lime, Plaster etc                                   |
|                     | 17 Basic metals and fabricated metal products                            |
|                     | 18 Machinery and equipment   |
|                     | 19 Electrical and optical equipment                                      |
|                     | 22 Other transport equipment   |
|                     | 23 Manufacturing not elsewhere classified                                |
|                     | 24 Recycling   |
|                     | 25 Electricity Supply  |
|                     | 26 Gas supply  |
|                     | 27 Water supply  |
|                     | 28 Construction  |
|                     | 29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and |
|                     | personal and household goods   |
|                     | 31 Transport, Storage and communication                                  |
|                     | 33 Information technology  |
|                     | 34 Engineering services  |

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| Scope Group         | IAF Codes   |  |
|---------------------|---|--|
|                     |   |  |
| Technical Cluster 3 | 32 Financial Intermediation, real estate, renting |  |
|                     | 35 Other services                                 |  |
|                     | 36 Public administration                          |  |
|                     | 37 Education                                      |  |
|                     | 38 Health & social work                           |  |
|                     | 39 Other social services                          |  |
| Technical Cluster 4 | 2 Mining and quarrying                            |  |
|                     | 11 Nuclear fuels                                  |  |
|                     | 20 Shipbuilding                                   |  |
|                     | 21 Aerospace                                      |  |

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### Annex no. 6: Scope for ISO 37001 Anti Bribery Management Systems Certification

| Scope Group         | Scope  |
|---------------------|--|
| Technical Cluster 1 | <ul> <li>Primary resources sectors include Agriculture, fishing, forestry, mining, quarrying</li> <li>Industrial sector</li> <li>Service sector</li> <li>Industrial &amp; service sector providing services to governmental/semi-</li> </ul>   |
|                     | governmental civil and military departments/organizations  Media including print, electronic, digital, social media and research organizations, survey/ poll companies, lobbying companies   |
| Technical Cluster 2 | <ul> <li>Financial services including banks, finance companies, investment<br/>companies, micro credit &amp; micro finance companies, insurance<br/>companies, customs and taxation authorities, financial auditing<br/>companies.</li> </ul>  |
|                     | <ul> <li>Public administration including all governmental<br/>departments/entities/organizations/utility service providers/security,<br/>health, education, civic service providers with and without regulatory<br/>roles.</li> </ul>  |
|                     | <ul> <li>Legal/justice/regulatory service providers.</li> <li>Semi-governmental organizations with and without regulatory roles.</li> <li>Governmental defense related organizations responsible for land, air, sea, cyber defenses.</li> <li>international/regional/local institutional funds and donor organizations.</li> </ul> |

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### 14 Annex no. 7: Scope for ISO 41001 Facility Management Systems Certification

| Scope Group         | Scope   |
|---------------------|---|
| To device Charten 1 |   |
| Technical Cluster 1 | Facility management in large commercial or residential communities where        |
|                     | the facility management company has more than 50 workers and staff.             |
|                     | Managed facilities may include cleaning, gardening, routine maintenance         |
|                     | including heating, ventilating, air conditioning (HVAC), electrical, plumbing & |
|                     | carpentry, reception & concierge service.                                       |
|                     | (Example: managing facilities in multiple buildings, parks (land scaped areas), |
|                     | common areas etc.)  |
| Technical Cluster 2 | Facility management in small residential or commercial communities where        |
|                     | the facility management company has less than 50 workers and staff.             |
|                     | Managed facilities may include cleaning, gardening, routine maintenance         |
|                     | including heating, ventilating, air conditioning (HVAC), electrical, plumbing & |
|                     | carpentry, reception & concierge service.                                       |
|                     | (Example: managing facilities in single buildings, land scaped areas etc)       |

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### 15 Annex no. 8: Scope for ISO 37301 Compliance Management Systems Certification

| Scope Group         | Scope  |  |
|---------------------|--|--|
| Technical Cluster 1 | Compliance management in financial organizations including banks, finance companies, investment companies, micro credit & micro finance companies, insurance companies, customs and taxation authorities, financial auditing                               |  |
| Technical Cluster 2 | companies.  Compliance management in non-financial highly regulated sectors including healthcare providers, pharmaceuticals, nuclear technology industry, communication service providers, law enforcement & defense organizations, public administration. |  |
| Technical Cluster 3 | Compliance management in other organizations including service sector, education, industry.  |  |

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### 16 Annex no. 9: Scope for ISO 13485 Medical Device Quality Management Systems Certification

### Table 1.1 - NON-ACTIVE MEDICAL DEVICES

| Main Technical                | Technical Areas                                      | Product Categories Covered by the Technical Areas  |
|-------------------------------|--|--|
| Areas                         |  |  |
| Non-Active<br>Medical Devices | General non-active, non- implantable medical devices | <ul> <li>Non-active devices for anaesthesia, emergency and intensive care</li> <li>Non-active devices for injection, infusion, transfusion and dialysis</li> <li>Non-active orthopedic and rehabilitation devices</li> <li>Non-active medical devices with measuring function</li> <li>Non-active ophthalmologic devices</li> <li>Non-active instruments</li> <li>Contraceptive medical devices</li> <li>Non-active medical devices for disinfecting, cleaning, rinsing</li> <li>Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)</li> <li>Non-active medical devices for ingestion</li> </ul> |
|                               | Non-active implants                                  | <ul> <li>Non-active cardiovascularimplants</li> <li>Non-active orthopedic implants</li> <li>Non-active functional implants</li> <li>Non-active soft tissue implants</li> </ul>   |
|                               | Devices for wound care                               | <ul> <li>Bandages and wound dressings</li> <li>Suture material and clamps</li> <li>Other medical devices for woundcare</li> </ul>  |
|                               | Non-active dental devices and accessories            | <ul> <li>Non-active dental devices/equipment and instruments</li> <li>Dental materials</li> <li>Dental implants</li> </ul>   |
|                               | Non-active medical devices otherthan specified above |  |

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### Table 1.2 - ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES

| Main Technical<br>Areas                  | Technical Areas   | Product Categories Covered bythe Technical Areas   |
|--|---|--|
| Active Medical Devices (Non-Implantable) | General active medical devices                                      | <ul> <li>Devices for extra-corporal circulation, infusion and haemopheresis</li> <li>Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia</li> <li>Devices for stimulation or inhibition</li> <li>Active surgical devices</li> <li>Active ophthalmologic devices</li> <li>Active dental devices</li> <li>Active devices for disinfection and sterilization</li> <li>Active rehabilitation devices and active prostheses</li> <li>Active devices for patient positioning and transport</li> <li>Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)</li> <li>Software, including software design for medical devices</li> <li>Medical gas supply systems and parts thereof</li> </ul> |
|  | Devices for imaging   | <ul><li>Devices utilizing ionizing radiation</li><li>Devices utilizing non-ionizing radiation</li></ul>  |
|  | Monitoring devices  Devices for radiation therapy andthermo therapy | <ul> <li>Monitoring devices of non-vital physiological parameters</li> <li>Monitoring devices of vital physiological parameters</li> <li>Devices utilising ionizing radiation</li> <li>Devices utilising non-ionizing radiation</li> <li>Devices for hyperthermia / hypothermia</li> </ul>   |
|  | Active (non-implantable) medical devices other than specified above | Devices for (extracorporal) shock- wave therapy (lithotripsy)  |

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### Table 1.3 - ACTIVE IMPLANTABLE MEDICAL DEVICES

| Main Technical<br>Areas | Technical Areas                   | Product Categories Covered bythe Technical Areas |
|-------------------------|-----------------------------------|--|
| Active                  | General active implantable        | Active implantable medical devices for           |
| Implantable             | medical devices                   | stimulation / inhibition                         |
| Medical Devices         |                                   | Active implantable medical devices delivering    |
|                         |                                   | drugs or othersubstances                         |
|                         |                                   | Active implantable medical devices               |
|                         |                                   | substituting or replacing                        |
|                         |                                   | organ functions                                  |
|                         | Implantable medical devices other |  |
|                         | than specified above              |  |

### Table 1.4 - IN VITRO DIAGNOSTIC MEDICAL DEVICES

| Main Technical<br>Areas | Technical Areas                        | Product Categories Covered bythe<br>Technical Areas |
|-------------------------|--|---|
| In Vitro                | Reagents and reagent products,         |   |
| Diagnostic              | calibrators and control materials for: |   |
| Medical Devices         | Clinical Chemistry Immunochemistry     |   |
| (IVD)                   | (Immunology)                           |   |
|                         | Haematology/Haemostasis/Im             |   |
|                         | munohematology Microbiology            |   |
|                         | Infectious Immunology                  |   |
|                         | Histology/Cytology Genetic Testing     |   |
|                         | In Vitro Diagnostic Instruments and    |   |
|                         | software                               |   |
|                         | IVD medical devices other than         |   |
|                         | specified above                        |   |

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### Table 1.5 - STERILIZATION METHODS FOR MEDICAL DEVICES

| Main Technical     | Technical Areas   | Product Categories Coveredby the |
|--------------------|---|----------------------------------|
| Areas              |   | Technical Areas                  |
| Sterilization      | Ethylene oxide gas sterilization                            |                                  |
| Method for Devices | (EOG)   |                                  |
|                    | Moist heat  |                                  |
|                    | Aseptic processing  |                                  |
|                    | Radiation sterilization (e.g., gamma, x-ray, electron beam) |                                  |
|                    | Low temperature steam and formaldehyde sterilization        |                                  |
|                    | Thermic sterilization with dry heat                         |                                  |
|                    | Sterilization with hydrogen peroxide                        |                                  |
|                    | Sterilization method other than specified above             |                                  |

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# Table 1.6 – DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES

| Main Technical<br>Areas     | Technical Areas   | Product Categories Covered bythe<br>Technical Areas |
|-----------------------------|---|---|
| Devices Incorporating/      | Medical devices incorporating medicinal substances  |   |
| Utilizing Specific          | Medical devices utilizing tissues of animal origin  |   |
| Substances/<br>Technologies | Medical devices incorporating derivates of human blood  |   |
|                             | Medical devices utilizing micromechanics  |   |
|                             | Medical devices utilizing nanomaterials   |   |
|                             | Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed          |   |
|                             | Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above. |   |

### Table 1.7 - PARTS AND SERVICES

| Main Technical<br>Areas | Technical Areas         | Product Categories Covered bythe Technical Areas  |
|-------------------------|-------------------------|---|
| Parts or Services       | Raw materials           | Raw metals, plastic, wood, ceramic  |
|                         | Components              | Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic                                 |
|                         | Subassemblies           | Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions                                      |
|                         | Calibration services *  | Verification/confirmation services for measuring instruments, tools or test fixtures  |
|                         | Distribution services   | Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.         |
|                         | Maintenance services    | Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks. |
|                         | Transportation services | Trucking, shipping, air transportation service in general.  |
|                         | Other services          | Consulting services related to medical devices, packaging services, etc.  |

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