Quality System Assessment Checklist

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| **DS/EN ISO 9001:2008 + AC:2009/2010** | : | Quality management systems – Requirements (EN ISO 9001:2008 + AC:2009) |
| **DS/EN ISO 13485:2012 +****AC:2012** | : | Medical devices – Quality management systems – Requirements for regulatory purposes (EN ISO 13485:2012 + AC:2012) |
| **DS/CEN ISO/TR 14969:2005** |  | Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003 (CEN ISO/TR 14969:2004) |
| **93/42/EEC** | : | EU Council Directive of 14 June 1993 concerning medical devices, as amended by 98/79/EC, 2000/70/EC, 2001/104/EC, 2003/12/EC and 2007/47/EC and by EC regulation No. 1882/2003 |
| **98/79/EC** |  | EU Council Directive of 27 October 1998 on in vitro diagnostic medical devices, as amended by EC regulation No. 1882/2003 |
| **ISB 1263** | : | Statutory Order of the Danish Ministry of the Interior and Health No 1263 of December 15, 2008 (transposing the MDD 93/42/EEC, as amended into Danish law) |
| **ISB 1269** |  | Statutory Order of the Danish Ministry of the Interior and Health No 1269 of December 12, 2005 (transposing the MDD 98/79/EC into Danish law) |

For

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| --- | --- |
| **Company Data:** |  |
| Company Name |  |
| File No |  |
| **Traceability:** |  |
| Documentation used for completing in the checklist |  |
| **Report documentation: (To be filled in by DGM)** |  |
| Pre-assessment report name/no. | Date |

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**Administrative data**

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| Requirement model (check applicable box) | 🞏 93/42/EEC (ISB 1263), Annex II (Full quality assurance)🞏 93/42/EEC (ISB 1263), Annex V (Production quality assurance)🞏 93/42/EEC (ISB 1263), Annex VI (Product quality assurance)🞏 98/79/EC (ISB 1269), Annex IV (Full quality assurance)🞏 98/79/EC (ISB 1269), Annex VII (Production quality assurance)🞏 DS/EN ISO 9001:2008 + AC:2009/2010 ( = EN ISO 9001:2008 + AC:2009 and ISO 9001:2008+ Corr. 2009)🞏 DS/EN ISO 13485:2012 + AC:2012( = EN ISO 13485:2012 + AC:2012 and ISO 13485:2003 + Corr. 2009) |
|  | 🞏 Other (e.g. sector requirement, specify): |
| Checklist used for (check applicable box) | 🞏 DGM Pre-assessment🞏 Approval/certification audit🞏 Post/after audit🞏 Pre-audit | 🞏 Inspection/Surveillance audit🞏 Supplementary audit/approval in connection with:🞏 Other: |
| Proposed Scope of the Assessment: |
| Regulatory requirements implemented in the quality system |
| Clauses excluded *or considered not applicable* as per ISO 9001:2008 + Corr. 2009/ISO 13485:2003 Corr. 2009 section 1.2 and justification for exclusion *and/or non-application*: |
| Clause(s) | Justification for **exclusion or non-application**:  |
| The undersigned lead auditor hereby confirms that the activities marked above have been carried out at all relevant sites, in conformity with the applicable internal DGM rules and the applicable accreditation and notification criteria for all relevant elements of the requirement model. The activities were adequately representative of all products, processes and services covered by the scope of the assessment.Date/signature: |
|  |
| Formatting of the questions in the checklist:* Question/requirements originating from ISO 9001:2008 + Corr. 2009 and ISO 13485:2003 + Corr. 2009 are in normal typeface.
* Question/requirements originating from ISO 9001:2008 + Corr. 2009 only, are underlined.
* *Question/requirements originating from ISO 13485:2003 + Corr. 2009 only are in Italic.*
* **Question/requirements originating from MDD/IVDD are in bold.**
 |

**Guidelines and notes**

Where the interpretation of a question gives rise to doubt, the text of the applicable standard/directive always applies.

The questions in the checklist are formatted as specified on previous page:

The requirements on each panel of this checklist appear from those found in the standard(s)/directive(s).

Requirements found in the ISB 1263 are included where it exceed or complement the basic requirements.

Abbreviations used:

|  |  |
| --- | --- |
| EFTA | European Free Trade Association  |
| EU & EEC | European Union (previously European Economic Community) |
| 93/42/EEC | The Medical Devices Directive (MDD) / EU Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended |
| ISB 1263 | The Danish Ministry of the Interior and Health implementation document No. 1263 of 15 December 2008. This document transposes the Council Directive 93/42/EEC, as amended, into Danish law. |
| ISB 1269 | The Danish Ministry of the Interior and Health implementation document No. 1269 of 12 December 2005. This document transposes the Council Directive 98/79/EC, as amended, into Danish law. |
| PMS | Post-Marketing Surveillance. A system to channel and review experience gained from devices in the post-production phase |
| Vigilance system | System to evaluate and report adverse incidents to Competent Authorities |
| GMDVS | EU Commission MEDDEV document regarding "Guidelines for Medical Device Vigilance System“ |
| 21CFR§820NA | United States Food and Drug Administration Quality System Regulation.Not Applicable |

***Please note that DGM reserves the right to change the checklist without further notice***

**Significant subcontractors (Manufacturer and/or DGM)**

Describe and define the functions performed by, and controls applied to, subcontractors which have a significant role in the design and/or production of the product(s). Provide the names of any Notified Bodies, which verified these controls.

**Company data**

|  |  |
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| Company name and AddressContact person | Phone:Email: |
| Functions performed: |
| Description of Implemented Controls and evaluation on the need for DGM to audit the subcontractor: |
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**Company data**

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| Company name and AddressContact person | Phone:Email: |
| Functions performed: |
| Description of Implemented Controls and evaluation on the need for DGM to audit the subcontractor: |
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**Company data**

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| --- | --- |
| Company name and AddressContact person | Phone:Email: |
| Functions performed: |
| Description of Implemented Controls and evaluation on the need for DGM to audit the subcontractor: |
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**Table of contents**

[4 Quality management system 7](#_Toc279654221)

[4.1. General requirements 7](#_Toc279654222)

[4.2. Documentation requirements 8](#_Toc279654223)

[4.2.1. General 8](#_Toc279654224)

[4.2.2. Quality manual 8](#_Toc279654225)

[4.2.3. Control of documents 9](#_Toc279654226)

[4.2.4. Control of records 10](#_Toc279654227)

[5. Management responsibility 11](#_Toc279654228)

[5.1. Management commitment 11](#_Toc279654229)

[5.2. Customer focus 11](#_Toc279654230)

[5.3. Quality policy 11](#_Toc279654231)

[5.4. Planning 12](#_Toc279654232)

[5.4.1. Quality objectives 12](#_Toc279654233)

[5.4.2. Quality management system planning 12](#_Toc279654234)

[5.5. Responsibility, authority and communication 12](#_Toc279654235)

[5.5.1. Responsibility and authority 12](#_Toc279654236)

[5.5.2. Management representative 12](#_Toc279654237)

[5.5.3. Internal communication 13](#_Toc279654238)

[5.6. Management review 13](#_Toc279654239)

[5.6.1. General 13](#_Toc279654240)

[5.6.2. Review input 14](#_Toc279654241)

[5.6.3. Review output 14](#_Toc279654242)

[6. Resource management 15](#_Toc279654243)

[6.1. Provision of resources 15](#_Toc279654244)

[6.2. Human resources 15](#_Toc279654245)

[6.2.1. General 15](#_Toc279654246)

[6.2.2. Competence, awareness and training (ISO 13485:2003) 15](#_Toc279654247)

[6.2.2. Competence, training and awareness (ISO 9001:2008) 15](#_Toc279654248)

[6.3. Infrastructure 16](#_Toc279654249)

[6.4. Work environment 16](#_Toc279654250)

[7. Product realization 17](#_Toc279654251)

[7.1. Planning of product realization 17](#_Toc279654252)

[7.2. Customer-related processes 17](#_Toc279654253)

[7.2.1. Determination of requirements related to the product 18](#_Toc279654254)

[7.2.2. Review of requirements related to the product 18](#_Toc279654255)

[7.2.3. Customer communication 18](#_Toc279654256)

[7.3. Design and development 20](#_Toc279654257)

[7.3.1. Design and development planning 20](#_Toc279654258)

[7.3.2. Design and development inputs 20](#_Toc279654259)

[7.3.3. Design and development outputs 21](#_Toc279654260)

[7.3.4. Design and development review 21](#_Toc279654261)

[7.3.5. Design and development verification 22](#_Toc279654262)

[7.3.6. Design and development validation 23](#_Toc279654263)

[7.3.7. Control of design and development changes 23](#_Toc279654264)

[7.4. Purchasing 24](#_Toc279654265)

[7.4.1. Purchasing process 24](#_Toc279654266)

[7.4.2. Purchasing information 24](#_Toc279654267)

[7.4.3. Verification of purchased product 24](#_Toc279654268)

[7.5. Production and service provision 25](#_Toc279654269)

[7.5.1. Control of production and service provision (ISO 9001:2008) 25](#_Toc279654270)

[7.5.1. Control of production and service provision (ISO 13485:2003) 25](#_Toc279654271)

[7.5.2. Validation of processes for production and service provision (ISO 9001:2008) 26](#_Toc279654272)

[7.5.2. Validation of processes for production and service provision (ISO 13485:2003) 27](#_Toc279654273)

[7.5.3. Identification and traceability (ISO 9001:2008) 27](#_Toc279654274)

[7.5.3. Identification and traceability (ISO 13485:2003) 28](#_Toc279654275)

[7.5.4. Customer property 29](#_Toc279654276)

[7.5.5. 7.5.5. Preservation of product 29](#_Toc279654277)

[7.6. Control of monitoring and measuring *devices*/equipment 30](#_Toc279654278)

[8. Measurement, analysis and improvement 31](#_Toc279654279)

[8.1. General 31](#_Toc279654280)

[8.2. Monitoring and measurement 32](#_Toc279654281)

[8.2.1. Customer satisfaction (ISO 9001:2008) 32](#_Toc279654282)

[8.2.1. Feedback (ISO 13485:2003) 32](#_Toc279654283)

[8.2.2. Internal audit 32](#_Toc279654284)

[8.2.3. Monitoring and measurement of processes 33](#_Toc279654285)

[8.2.4. Monitoring and measurement of product (ISO 9001:2008) 33](#_Toc279654286)

[8.2.4. Monitoring and measurement of product (ISO 13485:2003) 33](#_Toc279654287)

[8.3. Control of nonconforming product 35](#_Toc279654288)

[8.4. Analysis of data 36](#_Toc279654289)

[8.5. Improvement 37](#_Toc279654290)

[8.5.1. Continual improvement (ISO 9001:2008) 37](#_Toc279654291)

[8.5.1 General (ISO 13485:2003) 37](#_Toc279654292)

[8.5.2. Corrective action 38](#_Toc279654293)

[8.5.3. Preventive action 38](#_Toc279654294)

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| Quality management system |

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| General requirements | **Notes** |
| *Has the organization established, documented, implemented and maintained a quality management system and maintained its effectiveness in accordance with the requirements of this International Standard?* |  |
| Has the organization established, documented, implemented and maintained a quality management system and continually improved its effectiveness in accordance with the requirements of this International Standard? |  |
| Does the organization: |  |
| *a) Identify the processes needed for the quality management system and their application throughout the organization (see 1.2)?* |  |
| a) Determine the processes needed for the quality management system and their application throughout the organization (see 1.2)? |  |
| b) Determine the sequence and interaction of these processes? |  |
| c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective? |  |
| d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes? |  |
| *e) Monitor, measure and analyze these processes?* |  |
| e) Monitor, measure where applicable and analyze these processes? |  |
| *f) Implement actions necessary to achieve planned results and maintain the effectiveness of these processes?* |  |
| f) Implement actions necessary to achieve planned results and continual improvement of these processes? |  |
| Are these processes managed by the organization in accordance with the requirements of this International Standard? |  |
| *Where an organization chooses to outsource any process that affects product conformity with requirements has the organization ensured control over such processes?* |  |
| Where an organization chooses to outsource any process that affects product conformity to requirements has the organization ensured control over such processes? |  |
| *Is control of such outsourced processes identified within the quality management system (see 8.5.1)?* |  |
| Is type and extent of control to be applied to these outsourced processes defined within the quality management system? |  |
| *NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.* |  |
| NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement. |  |
| NOTE 2: An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party. |  |
| NOTE 3. Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such asa) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements,b) the degree to which the control for the process is shared,c) the capability of achieving the necessary control through the application of 7.4. |  |

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| Documentation requirements |

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| General | **Notes** |
| Does the quality management system documentation include: |  |
| a) Documented statements of a quality policy and quality objectives? |  |
| b) A quality manual? |  |
| *c) Documented procedures required by this International Standard?* |  |
| c) Documented procedures and records required by this International Standard? |  |
| *d) Documents needed by the organization to ensure the effective planning, operation and control of its processes?* |  |
| d) Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes? |  |
| *e) Records required by this International Standard (see 4.2.4)?* |  |
| *f) Any other documentation specified by national or regional regulations?**Including identification and implementation of regulatory requirements.(IAF MD09)* |  |
| *Has the organization established and maintained a file either containing or identifying documents defining product specifications and quality system requirements (see 4.2.3) for each type or model of medical device (or referring to it)?* |  |
| *Do these documents define the complete manufacturing process and, if applicable, installation and servicing?* |  |
| *Where this International Standard specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.* |  |
| NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document. |  |
| NOTE 2.*NOTE 1.*The extent of the quality management system documentation can differ from one organization to another due toa) the size of the organization and type of activitiesb) the complexity of processes and their interactions, andc) the competence of personnel. |  |
| NOTE 3.*NOTE 2.*The documentation can be in any form or type of medium |  |

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| Quality manual | **Notes** |
| Has the organization established and maintained a quality manual that includes: |  |
| *a) The scope of the quality management system, including details of and justification for any exclusion and/or non-application (see 1.2)?* |  |
| a) The scope of the quality management system, including details of and justification for any exclusion (see 1.2)? |  |
| b) The documented procedures established for the quality management system, or reference to them? |  |
| c) A description of the interaction between the processes of the quality management system? |  |
| *Does the quality manual outline the structure of the documentation used in the quality management system?* |  |
| **Has the organization/manufacturer implemented procedures for the preparation and control of the EC Declaration of Conformity in accordance with ISB 1263/MDD, Annex II, Annex V or Annex VI or with ISB 1269/IVD, Annex IV or Annex VII?** |  |

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| Control of documents | **Notes** |
| Are documents required by the quality management system controlled? |  |
| Are records controlled according to the requirements given in 4.2.4? |  |
| Has a documented procedure been established to define the controls needed: |  |
| *a) To review and approve documents for adequacy prior to issue?* |  |
| a) To approve documents for adequacy prior to issue? |  |
| b) To review and update as necessary and re-approve documents? |  |
| c) To ensure that changes and the current revision status of documents are identified? |  |
| d) To ensure that relevant versions of applicable documents are available at points of use? |  |
| e) To ensure that documents remain legible and readily identifiable? |  |
| *f) To ensure that documents of external origin are identified and their distribution controlled?**Including identification and implementation of regulatory requirements.(IAF MD09)* |  |
| f) To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled? |  |
| g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? |  |
| Accreditation requirement for DGM: Does the company destroy outdated versions of certificates issued by DGM |  |
| *Does the organization ensure that changes to documents are reviewed and approved either by the original approving function or another designated function?* |  |
| *Does the organization ensure that these functions have access to pertinent background information upon which to base its decisions?* |  |
| *Has the organization defined a retention period for at least one copy of obsolete controlled documents, which ensures that documents to which medical devices have been manufactured and tested are available for at least the lifetime (as defined by the organization) of the medical device or as specified by relevant regulatory requirements?* |  |
| *Is the retention time greater than or equal the retention time specified for records (see 4.2.4)?* |  |
| **Do procedures exist to control and deal with relevant standards and regulatory approval requirements, and are they available, updated and distributed to the persons concerned?** |  |
| **Is the technical documentation available and is the documentation integrated into the quality system in accordance with ISB 1263/MDD, Annex II section 4.2, (if class III product), Annex II section 6.1, Annex V section 5.1 or Annex VI section 5.1 or with ISB 1269/IVD, article 9, paragraph 7?** |  |
| **Does the organization/manufacturer or his authorized representative or the person responsible for placing the device on the EEC market meet the obligation to keep the technical documentation available to national authorities (ISB 1263/ISB 1269/ MDD, Annex II, section 6.3; Annex III, section 7.3 and 7.4; Annex I, section 13.3(a))?** |  |
| **Does the organization/manufacturer meet the requirement that relevant product and system documentation shall be retained for at least five years (15 years for implants) after the last product has been manufactured, cf. ISB 1263/ISB 1269/MDD, Annex II, section 6.1, Annex V, Section 5.1 or Annex VI, section 5.1 or cf. ISB 1269/IVD, article 9, paragraph 7?** |  |
| **Are changes to the product and/or system documentation assessed according to the requirements in ISB 1263/MDD or in ISB 1269/IVD, including the Essential Requirements and the risk analysis?** |  |
| **Has the manufacturer implemented procedures to ensure that the product list is kept up to date, and does the product list contain the following information: Reference to EC certificate and for each product the type identifier, the classifi­cation, the date the product placed on the market (w. CE mark) and a specification of which product group/family, as listed on the certificate, that covers the product.** |  |
| **Do requirement for notifying substantial changes of the product and/or system documentation to the Notified Body conform to ISB 1263/MDD, Annex II, section 3.4, Annex V, section 3.4, or Annex VI, section 3.4 or ISB 1269/IVD, Annex III, section 6.3, Annex IV, section 3.4, Annex V, section 6 and 6.1, or Annex VII, section 3.4? (Is the interpretation of substantial changes, by the company, correct)** |  |

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| Control of records | **Notes** |
| *a) Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system?* |  |
| a) Are records established to provide evidence of conformity to requirements and of the effective operation of the quality management system controlled? |  |
| b) Do records remain legible, readily identifiable and retrievable? |  |
| *c) Is a documented procedure established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?* |  |
| c) Has the organization established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records? |  |
| *Has the organization defined a retention period at least equivalent to the lifetime of the product (as defined by the organization) and which is minimum 2 years from the date of product release or as specified by relevant regulatory requirements?* |  |
| **Does the organization/manufacturer retain relevant quality records available to the national authorities, for a period ending at least five years (15 years for implantable devices) after the last product has been manufactured cf. ISB 1263/MDD, Annex II, section 6.1, Annex V, section 5.1 or Annex VI, section 5.1 or cf. ISB 1269/IVD, article 9, paragraph 7?** |  |

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| Management responsibility |

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| Management commitment | **Notes** |
| *Does top management provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by:* |  |
| Does top management provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by: |  |
| a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements? |  |
| b) Establishing a quality policy? |  |
| c) Ensuring that quality objectives are established? |  |
| d) Conducting management reviews? |  |
| e) Ensuring the availability of resources? |  |
| *Note (ISO 13485:2003) For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.* |  |

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| Customer focus | **Notes** |
| *Does top management ensure that customer requirements are determined and are met (see 7.2.1 and 8.2.1)?* |  |
| Has top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)? |  |

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| Quality policy | **Notes** |
| Does top management ensure that the quality policy: |  |
| a) Is appropriate to the purpose of the organization? |  |
| *b) Includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system?* |  |
| b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system? |  |
| c) Provides a framework for establishing and reviewing quality objectives? |  |
| d) Is communicated and understood within the organization? |  |
| e) Is reviewed for continuing suitability? |  |
| **Has the organization/manufacturer addressed conformance to ISB 1263/MDD or to ISB 1269/IVD in the Quality Policy, including a regulatory conformance policy on which the quality system is based (Specification of which quality system Annex is used)?** |  |

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| Planning |

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| Quality objectives | **Notes** |
| Does top management ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization? |  |
| Are the quality objectives measurable and consistent with the quality policy? |  |

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| Quality management system planning | **Notes** |
| a) Does top management ensure that the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives? |  |
| b) Does top management ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? |  |

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| Responsibility, authority and communication |

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| Responsibility and authority | **Notes** |
| Does top management ensure that responsibilities and authorities are defined and communicated within the organization? |  |
| *Has top management established the interrelation of all personnel who manage, perform and verify work affecting quality, and does top management ensure the independence and authority necessary to perform these tasks?* |  |
| *NOTE: National or regional regulation might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.2).* |  |
| **Has the responsibility and the authority of the manufacturer with respect to the requirement in ISB 1263/ISB 1269/MDD article 1 (f)) been defined (see also Annex II and V, section 3.2 b; Annex VI, section 3.2)?** |  |

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| Management representative | **Notes** |
| *Has top management appointed a member of the management who, irrespective of other responsibilities, has been assigned responsibility and authority that includes:* |  |
| Has top management appointed a member of the organization’s management who, irrespective of other responsibilities, has been assigned responsibility and authority that includes: |  |
| a) Ensuring that processes needed for the quality management system are established, implemented and maintained? |  |
| *b) Reporting to top management on the performance of the quality management system and any need for improvement (see 8.5)?* |  |
| b) Reporting to top management on the performance of the quality management system and any need for improvement? |  |
| *c) Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization?* |  |
| c) Ensuring the promotion of awareness customer requirements throughout the organization? |  |
| NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system. |  |

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| Internal communication | **Notes** |
| Does top management ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system? |  |

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| Management review |

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| General | **Notes** |
| Does top management review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? |  |
| Does this review include assessing opportunities for improvement and the need for chan­ges to the quality management system, including the quality policy and quality objectives? |  |
| Are records from management reviews maintained (see 4.2.4)? |  |
| **Are measures implemented to verify and improve the effectiveness of the quality system with respect to the requirements of the MDD concerning e.g.: quality of design, production, product, control of non-conforming products and PMS/Vigilance (ISB 1263/MDD, Annex II, section 3.2 b; Annex V, section 3.2b; Annex VI, section 3.2, 3rd intent or ISB 1269/IVD, Annex IV, section 3.2 b; Annex VII, section 3.2b;)?** |  |
| **Does conformance to both the product and Quality System requirements in ISB 1263/MDD or ISB 1269/IVD form part of the management review?** |  |
| **Do requirement for notifying substantial changes of the product and Quality system to the Notified Body form part of the management review?****(ISB 1263/MDD, Annex II, section 3.4, Annex V, section 3.4, or Annex VI, section 3.4 or ISB 1269/IVD, Annex III, section 6.3, Annex IV, section 3.4, Annex V, section 6 and 6.1, or Annex VII, section 3.4)****- Is the interpretation of substantial changes, by the company, correct?** |  |

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| Review input | **Notes** |
| Does the input to management review include information on: |  |
| a) Results of audits? |  |
| b) Customer feedback? |  |
| c) Process performance and product conformity? |  |
| d) Status of preventive and corrective actions? |  |
| e) Follow-up actions from previous management reviews? |  |
| f) Changes that could affect the quality management system? |  |
| g) Recommendations for improvement? |  |
| *h) New or revised regulatory requirements?* |  |

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| Review output | **Notes** |
| Does the output from the management review include any decisions and actions related to: |  |
| *a) Improvements needed to maintain the effectiveness of the quality management system and its processes?* |  |
| a) Improvement of the effectiveness of the quality management system and its processes? |  |
| b) Improvement of product related to customer requirements? |  |
| c) Resource needs? |  |

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| Resource management |

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| Provision of resources | **Notes** |
| Does the organization determine and provide the resources needed: |  |
| *a) To implement the quality management system and to maintain its effectiveness?* |  |
| *b) To meet regulatory and customer requirements?* |  |
| a) To implement and maintain the quality management system and continually improve its effectiveness? |  |
| b) To enhance customer satisfaction by meeting customer requirements? |  |

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| Human resources |

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| General | **Notes** |
| *Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience?* |  |
| Are personnel performing work affecting conformity product requirements competent on the basis of appropriate education, training, skills and experience? |  |
| NOTE: Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system. |  |

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| Competence, awareness and training (ISO 13485:2003) | **Notes** |
| 6.2.2. Competence, training and awareness (ISO 9001:2008) |  |
| Does the organization: |  |
| *a) Determine the necessary competence for personnel performing work affecting product quality?* |  |
| a) Determine the necessary competence for personnel performing work affecting conformity to product requirements? |  |
| *b) Provide training or take other actions to satisfy these needs?* |  |
| b) Where applicable, provide training or take other actions to achieve the necessary competence? |  |
| c) Evaluate the effectiveness of the actions taken? |  |
| d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? |  |
| e) Maintain appropriate records of education, training, skills and experience (see 4.2.4)? |  |
| *NOTE (ISO 13485:2003) National or regional regulations might require the organization to establish documented procedures for identifying training needs.* |  |

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| Infrastructure | **Notes** |
| Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements? |  |
| Does the infrastructure include, as applicable: |  |
| a) Buildings, workspace and associated utilities? |  |
| b) Process equipment (both hardware and software)? |  |
| *c) Supporting services (such as transport or communication)?* |  |
| c) Supporting services (such as transport or communication or information systems)? |  |
| *Has the organization established documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality?* |  |
| *Are records of such maintenance maintained (see 4.2.4)?* |  |

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| Work environment | **Notes** |
| Does the organization determine and does it manage the work environment needed to achieve conformity to product requirements? |  |
| *The following requirements applies:* |  |
| *a) Has the organization established documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).* |  |
| *b) If work environment conditions can have an adverse effect on product quality, has the organization established documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).* |  |
| *c) Does the organization ensure that all personnel who are required to work temporarily under special environmental conditions, within the work environment, are appropriately trained or supervised by a trained person [see 6.2.2 b)].* |  |
| *d) If appropriate, has special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).* |  |
| NOTE (ISO 9001:2008): The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather) |  |

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| Product realization |

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| Planning of product realization | **Notes** |
| Does the organization plan and develop the processes needed for product realization? |  |
| Is the planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1)? |  |
| In planning product realization, has the organization determined the following, as appropriate: |  |
| a) Quality objectives and requirements for the product? |  |
| *b) The need to establish processes, documents, and provide resources specific to the product?* |  |
| b) The need to establish processes and documents, and to provide resources specific to the product? |  |
| *c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance?* |  |
| c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance? |  |
| d) Records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4)? |  |
| Is the output of this planning in a form suitable for the organization’s method of operations? |  |
| *Has the organization established documented requirements for risk management throughout product realization?* |  |
| *Are records arising from risk management maintained (see 4.2.4 and Note 3)?* |  |
| **Have risk management procedures, in accordance with EN ISO 14971:2009, been implemented?** |  |
| **Does quality planning reflect the special activities in connection with observing ISB 1263/MDD or ISB 1269/IVD, e.g. for the preparation of technical documentation, testing and inspection?** |  |
| **Are the Essential Requirements of ISB 1263/MDD, Annex I, or of ISB 1269/IVD, Annex I, input to the planning of the inspection activities?** |  |
| **Are harmonized standards (e.g. safety requirements for active medical devices EN 60601-x-x or EN 61010-2-xx) used in connection with product testing?** |  |
| **Do procedures exist to establish clinical data as required by ISB 1263/MDD, Annex X, section 1 and current MEDDEV. 2.7.1 Rev.3, “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| **Do procedures exist, where relevant, for the conduct and approval of clinical investigations (cf. ISB 1263/MDD, article 15 & Annex X, section 2 and the harmonized standards EN ISO 14155-1/2:2003 and MEDDEV. 2.7.1 Rev.3, “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes. |  |
| *NOTE 3 (ISO 13485:2003) See ISO 14971 for guidance related to risk management.* |  |

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| Customer-related processes |

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| Determination of requirements related to the product | **Notes** |
| Does the organization determine: |  |
| a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities? |  |
| b) Requirements not stated by the customer but necessary for specified or intended use, where known? |  |
| *c) Statutory and regulatory requirements related to the product?* |  |
| c) Statutory and regulatory requirements applicable to the product? |  |
| *d) Any additional requirements determined by the organization?* |  |
| d) Any additional requirements considered necessary by the organization? |  |
| NOTE (ISO 9001:2008): Post-delivery activities include for example, actions under warranty provisions, contrac­tual obligations such as maintenance services and supplementary services such as recycling or final disposal. |  |
| **Is it ensured that only products meeting the requirements in ISB 1263/MDD or in ISB 1269/IVD can be released and marketed in EEC countries? This applies in particular to requirements related to language of information provided with the product by the manufacturer to the user (instruction for use and labeling).** |  |

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| Review of requirements related to the product | **Notes** |
| Does the organization review the requirements related to the product? |  |
| Is this review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that: |  |
| *a) Product requirements are defined and documented?* |  |
| a) Product requirements are defined? |  |
| b) Contract or order requirements differing from those previously expressed are resolved? |  |
| c) The organization has the ability to meet the defined requirements? |  |
| Are the records of the results of the review and actions arising from the review maintained (see 4.2.4)? |  |
| Where the customer provides no documented statement of requirement are the customer requirements confirmed by the organization before acceptance? |  |
| Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements? |  |
| NOTE In some situations, such as internet sales, a formal review is impractical for each order. In­stead the review can cover relevant product information such as catalogues or advertising material. |  |

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| Customer communication | **Notes** |
| Does the organization determine and has it implemented effective arrangements for communicating with customers in relation to: |  |
| a) Product information? |  |
| b) Enquiries, contracts or order handling, including amendments? |  |
| *c) Customer feedback, including customer complaints (see 8.2.1)?* |  |
| c) Customer feedback, including customer complaints? |  |
| *d) Advisory notices (see 8.5.1)?* |  |

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| Design and development |

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| Design and development planning | **Notes** |
| *Has the organization established documented procedures for design and development?* |  |
| Does the organization plan and control the design and development of product? |  |
| During the design and development planning, does the organization determine: |  |
| a) The design and development stages? |  |
| *b) The review, verification, validation and design transfer activities (see Note) that are appropriate at each design and development stage?* |  |
| b) The review, verification and validation that is appropriate to each design and development stage? |  |
| c) The responsibilities and authorities for design and development? |  |
| Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility? |  |
| Is planning output updated, as appropriate, as the design and development progresses (see 4.2.3)? |  |
| *Is planning output documented, and updated as appropriate, as the design and development progresses (see 4.2.3)?* |  |
| **Does a procedure exist for project planning, including integration and verification/ validation of fulfillment of Essential Requirements as per ISB 1263/MDD, Annex I or as per ISB 1269/IVD, Annex I?** |  |
| **Have all procedural and documentation requirements specified in ISB 1263/MDD, Annex II, section 3.2 or in ISB 1269/IVD, Annex IV, section 3.2 been implemented in the quality system, including requirements for preparation and compilation of technical documentation?** |  |
| *NOTE (ISO 13485:2003) Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.* |  |
| NOTE (ISO 9001:2008) Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization. |  |

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| Design and development inputs | **Notes** |
| Are inputs relating to product requirements determined and records maintained (see 4.2.4)? |  |
| *Do these inputs include:* |  |
| Do the inputs include: |  |
| *a) Functional, performance and safety requirements, according to the intended use?* |  |
| a) Functional and performance requirements? |  |
| b) Applicable statutory and regulatory requirements? |  |
| c) Where applicable, information derived from previous similar designs? |  |
| d) Other requirements essential for design and development? |  |
| *e) Output(s) of risk management (see 7.1)?* |  |
| Are these inputs reviewed for adequacy? |  |
| *Are these inputs reviewed for adequacy and approved?* |  |
| Are the requirements complete, unambiguous and not in conflict with each other? |  |
| **Does a procedure exist for determining whether the product is a medical device (according to ISB 1263/MDD, article 1) and if so, the risk classification of the product (according to ISB 1263/MDD, article 9) or an in vitro diagnostic medical device (according to ISB 1269/IVD, article 2,) and if so, whether it is for self evaluation or belongs to ISB 1269/IVD, Annex II, list A or list B,? Is the result documented in the technical documentation of the product (see also clause 4.2.1)?** |  |
| **Are the Essential Requirements of ISB 1263/MDD, Annex I or of ISB 1269/IVD, Annex I (including national language requirements), used as design input?** |  |
| **Have risk management procedures, in accordance with EN ISO 14971:2009, been implemented?** |  |

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| Design and development outputs | **Notes** |
| *Are the outputs of design and development provided in a form that enables verification against the design and development input and is it approved prior to release?* |  |
| Are the outputs of design and development in a form suitable for verification against the design and development input and is it approved prior to release? |  |
| Do the design and development outputs: |  |
| a) Meet the input requirements for design and development? |  |
| b) Provide appropriate information for purchasing, production and service provision? |  |
| c) Contain or reference product acceptance criteria? |  |
| d) Specify the characteristics of the product that are essential for its safe and proper use? |  |
| *Are records of the design and development outputs maintained (see 4.2.4)?* |  |
| **Does the design output, including the risk analysis, show that the identified risks have been reduced to an acceptable minimum?** |  |
| **Is it verified that the product meets all relevant Essential Requirements imposed in connection with the definition of the design input (see 7.3.2)?** |  |
| *NOTE (ISO 13485:2003) Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.* |  |
| NOTE (ISO 9001:2008) Information for production and service provision can include details for the preservation of product. |  |

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| Design and development review | **Notes** |
| Are systematic reviews of design and development performed at suitable stages in accordance with planned arrangements, with the purpose (see 7.3.1): |  |
| a) To evaluate the ability of the results of design and development to meet requirements? |  |
| b) To identify any problems and propose necessary actions? |  |
| Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed? |  |
| *Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1)?* |  |
| Are records of the results of the reviews and any necessary actions maintained (see 4.2.4)? |  |
| **Are relevant Essential Requirements evaluated in connection with the design review, including requirements for technical documentation?** |  |

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| Design and development verification | **Notes** |
| Is the verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements? |  |
| Are records of the results of the verification and any necessary actions maintained (see 4.2.4)? |  |

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| Design and development validation | **Notes** |
| *Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use?* |  |
| *Is validation completed prior to the delivery or implementation of the product (see Note 1)?* |  |
| Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known? |  |
| Is validation completed prior to the delivery or implementation of the product, wherever practicable? |  |
| Are records of the results of validation and any necessary actions maintained (see 4.2.4)? |  |
| *Does the organization perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2), as part of design and development validation?* |  |
| **Do procedures exist to establish clinical data as required by ISB 1263/MDD, Annex X, section 1 and current MEDDEV. 2.7.1 Rev.3, “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| **Do procedures exist, where relevant, for the conduct and approval of clinical investigations (cf. ISB 1263/MDD, article 15 & Annex X, section 2 and the harmonized standards EN ISO 14155-1/2:2003 and MEDDEV. 2.7.1 Rev.3, “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| *NOTE 1(ISO 13485:2003) If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.**NOTE 2 (ISO 13485:2003) Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.* |  |

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| Control of design and development changes | **Notes** |
| Are design and development changes identified and records maintained? |  |
| Are the changes reviewed, verified and validated, as appropriate, and approved before implementation? |  |
| Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered? |  |
| Are records of the results of the review of changes and any necessary actions maintained (see 4.2.4)? |  |
| **Do procedures exist for assessment of the effect of design changes on the Essen­tial Requirements of ISB 1263/MDD, Annex I, or of ISB 1269/IVD, Annex I including the risk analysis & intended use and are substantial changes reported to DGM (Is the interpretation of substantial changes, by the company, correct)?** |  |

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| Purchasing |

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| Purchasing process | **Notes** |
| *Has the organization established documented procedures to ensure that purchased product conforms to specified purchase requirements?* |  |
| Does the organization ensure that purchased product conforms to specified purchase requirements? |  |
| Is the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product? |  |
| Does the organization evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements? |  |
| Are criteria for selection, evaluation and re-evaluation established? |  |
| Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4)? |  |

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| Purchasing information | **Notes** |
| Does purchasing information describe the product to be purchased, including (where appropriate): |  |
| a) Requirements for approval of product, procedures, processes and equipment? |  |
| b) Requirements for qualification of personnel? |  |
| c) Quality management system requirements? |  |
| Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier? |  |
| *Does the organization, to the extent required for the traceability given in 7.5.3.2, maintain relevant purchasing information i.e. documents (see 4.2.3) and records (see 4.2.4)?* |  |
| **If relevant, are requirements specified for technical documentation to be provided by suppliers/subcontractor to ensure conformity with the documentation require­ments in ISB 1263/ISB 1269/MDD, Annex II, section 3.2.c); and/or Annex VII, section 3?** |  |

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| Verification of purchased product | **Notes** |
| Has the organization established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements? |  |
| Where the organization or its customer intends to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of product release in the purchasing information? |  |
| *Are records of the verification maintained (see 4.2.4)?* |  |
| **Is supplied technical documentation, if any, verified in relation to specified requirements (ISB 1263/ISB 1269/MDD, Annex II, section 3.2 c; Annex III, section 3; Annex VII, section 3)?** |  |

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| Production and service provision |

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| Control of production and service provision (ISO 9001:2008) | **Notes** |
| Does the organization plan and carry out production and service provision under controlled conditions? |  |
| Do the controlled conditions include, as applicable: |  |
| a) The availability of information that describes the characteristics of the product? |  |
| b) The availability of work instructions, as necessary? |  |
| c) The use of suitable equipment? |  |
| d) The availability and use of monitoring and measuring equipment? |  |
| e) The implementation of monitoring and measurement? |  |
| f) The implementation of product release, delivery and post-delivery activities? |  |

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| 7.5.1. Control of production and service provision (ISO 13485:2003) |  |
| 7.5.1.1. General requirements (ISO 13485:2003) | **Notes** |
| *Does the organization plan and carry out production and service provision under controlled conditions?* |  |
| *Do the controlled conditions include, as applicable:* |  |
| *a) The availability of information that describes the characteristics of the product?* |  |
| *b) The availability of documented procedures, documented requirements, work instructions and reference materials and reference measurement procedures, as necessary*  |  |
| *c) The use of suitable equipment?* |  |
| *d) The availability and use of monitoring and measuring devices?* |  |
| *e) The implementation of monitoring and measurement?* |  |
| *f) The implementation of release, delivery and post-delivery activities?* |  |
| *g) The implementation of defined operations for labeling and packaging?* |  |
| *Has the organization established and does it maintain a record (see 4.2.4) for each batch of medical devices?* |  |
| *Does the record provide traceability to the extent specified in 7.5.3 and does it identify the amount manufactured and amount approved for distribution?* |  |
| *Is the batch record verified and approved?* |  |
| *NOTE (13485) A batch can be a single medical device.* |  |
| **If relevant, does the technical documentation required in ISB 1263/MDD, Annex III or Annex VII or in ISB 1269/IVD, Annex III or Annex V, form basis for the production process, e.g. concerning test for compliance with the Essential Requirements of Annex I?** |  |
| 7.5.1.2. Control of production and service provision — Specific requirements (ISO 13485:2003) |  |
| 7.5.1.2.1. Cleanliness of product and contamination control (ISO 13485:2003) | **Notes** |
| *Has the organization established documented requirements for cleanliness of product if:* |  |
| *a) Product is cleaned by the organization prior to sterilization and/or its use? or* |  |
| *b) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use? or* |  |
| *c) Product is supplied to be used non-sterile and its cleanliness is of significance in use? Or* |  |
| *d) Process agents are to be removed from product during manufacture?* |  |
| *If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.* |  |
| 7.5.1.2.2. Installation activities (ISO 13485:2003) | **Notes** |
| *If appropriate, has the organization established documented requirements, which contain acceptance criteria for installing and verifying the installation of the medical device?* |  |
| *If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, has the organization provided documented requirements for installation and verification?* |  |
| *Are records of installation and verification performed by the organization or its authorized agent maintained (see 4.2.4)?* |  |
| 7.5.1.2.3. Servicing activities (ISO 13485:2003) | **Notes** |
| *If servicing is a specified requirement, has the organization established documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and for verifying that they meet the specified requirements?* |  |
| *Are records of servicing activities carried out by the organization maintained (see 4.2.4)?* |  |
| *NOTE Servicing can include, for example, repair and maintenance.* |  |
| 7.5.1.3. Particular requirements for sterile medical devices (ISO 13485:2003) | **Notes** |
| *Does the organization maintain records (see 4.2.4) of the process parameters for the sterilization process, which was used for each sterilization batch (see 4.2.4)?* |  |
| *Are sterilization records traceable to each production batch of medical devices (see 7.5.1.1)?* |  |

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| Validation of processes for production and service provision (ISO 9001:2008) | **Notes** |
| Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, where deficiencies become apparent only after the product is in use or the service has been delivered |  |
| Does the validation demonstrate the ability of these processes to achieve planned results? |  |
| Does the organization establish arrangements for these processes including, as applicable: |  |
| a) Defined criteria for review and approval of the processes? |  |
| b) Approval of equipment and qualification of personnel? |  |
| c) Use of specific methods and procedures? |  |
| d) Requirements for records (see 4.2.4)? |  |
| e) Revalidation? |  |

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| 7.5.2. Validation of processes for production and service provision (ISO 13485:2003) |  |
| 7.5.2.1. General requirements (ISO 13485:2003) | **Notes** |
| *Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?**Does this include any processes where deficiencies become apparent only after the product is in use or the service has been delivered?* |  |
| *Does the validation demonstrate the ability of these processes to achieve planned results?* |  |
| *Does the organization establish arrangements for these processes including, as applicable:* |  |
| *a) Defined criteria for review and approval of the processes?* |  |
| *b) Approval of equipment and qualification of personnel?* |  |
| *c) Use of specific methods and procedures?* |  |
| *d) Requirements for records (see 4.2.4)?* |  |
| *e) Revalidation?* |  |
| *Has the organization established documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements..* |  |
| *Are such software applications validated prior to initial use?* |  |
| *Are the results of validation recorded (see 4.2.4)?* |  |
| 7.5.2.2. Particular requirements for sterile medical devices (ISO 13485:2003) | **Notes** |
| *Has the organization established documented procedures for the validation of sterilization processes?* |  |
| *Have sterilization processes been validated prior to initial use?* |  |
| *Are records of the results of each sterilization process validation(s) maintained (see 4.2.4)?* |  |
| **Were harmonized standards used in connection with validation and monitoring of the sterilization process (e.g. EN 550/EN ISO 11135-1, EN 552/EN ISO 11137-1, and EN 554/EN ISO 17665-1)?** |  |

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| Identification and traceability (ISO 9001:2008) | **Notes** |
| Does the organization identify the product by suitable means throughout product realization, where appropriate? |  |
| Does the organization identify the product status with respect to monitoring and measurement requirements throughout product realization? |  |
| Where traceability is a requirement, does the organization control the unique identification of the product and maintain records (see 4.2.4)? |  |
| NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained. |  |

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| 7.5.3. Identification and traceability (ISO 13485:2003) |  |
| 7.5.3.1. Identification (ISO 13485:2003) | **Notes** |
| *Does the organization identify the product by suitable means throughout product realization, and has it established documented procedures for such product identification?* |  |
| *Has the organization established documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming products [see 6.4 d)]?* |  |
| 7.5.3.2. Traceability (ISO 13485:2003) |  |
| 7.5.3.2.1. General (ISO 13485:2003) | **Notes** |
| *Has the organization established documented procedures for traceability?* |  |
| *Do such procedures define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).* |  |
| *Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4)?* |  |
| *NOTE Configuration management is a means by which identification and traceability can be maintained.* |  |
| **Is traceability of products ensured (contractual) in those cases where external parties are used for the distribution of CE marked products?** |  |
| 7.5.3.2.2. Particular requirements for active implantable medical devices and implantable medical devices (ISO 13485:2003) | **Notes** |
| *Does the organization include records of all components, materials and work environment conditions, in defining the records required for traceability, if these could cause the medical device not to satisfy its specified requirements?* |  |
| *Does the organization require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such record are available for inspection?* |  |
| *Does the organization ensure that the name and address of the shipping package consignee is maintained (see 4.2.4)?* |  |
| 7.5.3.3. Status identification (ISO 13485:2003) | **Notes** |
| *Does the organization identify the product status with respect to monitoring and measurement requirements?* |  |
| *Is the identification of product status maintained throughout production, storage, installation, and servicing of the product to ensure that only products that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed?* |  |

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| Customer property | **Notes** |
| Does the organization exercise care with customer property while it is under the organization's control or being used by the organization? |  |
| Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product? |  |
| *If any customer property is lost, damaged or otherwise found to be unsuitable for use, is this reported to the customer and records maintained (see 4.2.4)?* |  |
| If any customer property is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer and maintain records (see 4.2.4)? |  |
| *NOTE (ISO 13485:2003) Customer property can include intellectual property or confidential health information.*NOTE (ISO 9001:2008) Customer property can include intellectual property and personal data. |  |

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| 7.5.5. Preservation of product | **Notes** |
| *Has the organization established documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination?* |  |
| Does the organization preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements? |  |
| *Does this preservation include identification, handling, packaging, storage and protection?* |  |
| As applicable, does this preservation include identification, handling, packaging, storage and protection? |  |
| Does preservation also apply to the constituent parts of a product? |  |
| *Has the organization established documented procedures or documented work instructions for the control of product with a limited shelf life or requiring special storage conditions?* |  |
| *Are special storage conditions controlled and recorded (see 4.2.4)?* |  |
| **Has procedures been implemented to ensured, where relevant, that labeling and instructions for use are translated correctly into foreign national languages versions according to the intended plan for placing the product on the marked?** |  |
| **Is it ensured, where relevant, that requirements for e.g. national language versions are checked and controlled in connection with dispatch, storage, etc.?** |  |

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| Control of monitoring and measuring *devices*/equipment | **Notes** |
| *Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1)?* |  |
| Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements? |  |
| *Has the organization established documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?* |  |
| Has the organization established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements? |  |
| Where necessary to ensure valid results, is measuring equipment: |  |
| *a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards?* *Where no such standards exist, is the basis used for calibration or verification recorded.* |  |
| a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards? Where no such standards exist, is the basis used for calibration or verification recorded (see 4.2.4). |  |
| b) Adjusted or re-adjusted as necessary? |  |
| *c) Identified to enable the calibration status to be determined?* |  |
| c) Have identification in order to determine its calibration status? |  |
| d) Safeguarded from adjustments that would invalidate the measurement result? |  |
| e) Protected from damage and deterioration during handling, maintenance and storage? |  |
| In addition, does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements? |  |
| Has the organization taken appropriate action on the equipment and any product affected? |  |
| Are records of the results of calibration and verification maintained (see 4.2.4)? |  |
| When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed? |  |
| Is this undertaken prior to initial use and reconfirmed as necessary? |  |
| *NOTE (ISO 13485:2003) See ISO 10012 for guidance.*NOTE (9001:2008) Conformity of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use. |  |

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| Measurement, analysis and improvement |

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| General | **Notes** |
| Has the organization planed and implemented the monitoring, measurement, analysis and improvement processes needed: |  |
| *a) To demonstrate conformity of the product?* |  |
| a) To demonstrate conformity to product requirements? |  |
| b) To ensure conformity of the quality management system? |  |
| c) To continually improve the effectiveness of the quality management system? |  |
| *c) To maintain the effectiveness of the quality management system.* |  |
| Does this include determination of applicable methods, including statistical techniques, and the extent of their use? |  |
| *NOTE (ISO 13485:2003) National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.* |  |
| **Are the Essential Requirements of ISB 1263/MDD, Annex I or of ISB 1269/IVD, Annex I, input to the planning of the inspection activities?** |  |
| **Are harmonized standards (e.g. safety requirements for active medical devices EN 60601-x-x or EN 61010-x-x) used in connection with testing of product?** |  |

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| Monitoring and measurement |

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| Customer satisfaction (ISO 9001:2008) | **Notes** |
| As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements? |  |
| Are the methods for obtaining and using this information determined? |  |
| NOTE☹ISO 9001:2008) monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports. |  |

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| 8.2.1. Feedback (ISO 13485:2003) | **Notes** |
| *As one of the measurements of the performance of the quality management system, does the organization monitor information relating to whether the organization has met customer requirements?* |  |
| *Are the methods for obtaining and using this information determined?* |  |
| *Has the organization established a documented procedure for a feedback system [see 7.2.3 c)] to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3)?* |  |
| *If national or regional regulations require the organization to gain experience from the post-production phase, does the review of this experience form part of the feedback system (see 8.5.1)?* |  |

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| Internal audit | **Notes** |
| Does the organization conduct internal audits at planned intervals to determine whether the quality management system: |  |
| a) Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? |  |
| b) Is effectively implemented and maintained? |  |
| Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? |  |
| Are the audit criteria, scope, frequency and methods defined? |  |
| *Does selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process?* |  |
| Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process? |  |
| Do auditors not audit their own work? |  |
| *Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure?* |  |
| Is a documented procedure established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results? |  |
| Are records of the audits and their results maintained? |  |
| *Does the management responsible for the area being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes?* |  |
| Does the management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes? |  |
| Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2)? |  |
| **Do the planned quality audits include all activities required in ISB 1263/MDD, Annex II (section 3.2b, 2nd indent), ISB 1263/MDD, Annex V (section 3.2b, 2nd indent) or ISB 1263/MDD, Annex VI (section 3.2, 3rd indent) or in ISB 1269/MDD, Annex 4 (section 3.2b, 2nd indent), ISB 1269/IVD, Annex VII (section 3.2b, 2nd indent)?** |  |
| NOTE See ISO 19011 for guidance*NOTE See ISO 19011 for guidance related to quality auditing.* |  |

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| Monitoring and measurement of processes | **Notes** |
| Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes? |  |
| Do these methods demonstrate the ability of the processes to achieve planned results? |  |
| *When planned results are not achieved, are correction and corrective action taken, as appropriate, to ensure conformity of the product?* |  |
| When planned results are not achieved, are correction and corrective action taken, as appropriate? |  |
| NOTE (ISO 9001:2008): When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system. |  |

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| Monitoring and measurement of product (ISO 9001:2008) | **Notes** |
| Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met? |  |
| Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1)? |  |
| Is evidence of conformity with the acceptance criteria maintained (see 4.2.4)? |  |
| Do records indicate the person(s) authorizing release of product for delivery to customer (see 4.2.4)? |  |
| Do the release of product and delivery of service to the customer not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer? |  |

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| 8.2.4. Monitoring and measurement of product (ISO 13485:2003) | **Notes** |
| 8.2.4.1 General requirements |  |
| *Does the organization monitor and measure the characteristics of the product in order to verify that product requirements have been met?* |  |
| *Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1)?* |  |
| *Is evidence of conformity with the acceptance criteria maintained?* |  |
| *Do records indicate the person(s) authorizing release of product (see 4.2.4)?* |  |
| *Is it ensured that product release and service delivery do not proceed until the planned arrangements (see 7.1) have been satisfactorily completed?* |  |
| **Is supplied technical documentation, if any, verified in relation to specified requirements (ISB 1263/MDD, Annex II, section 3.2 c; Annex III, section 3; Annex VII, section 3 or ISB 1269/IVD, Annex III, section 3; Annex IV, section 3.2 c; Annex V, section 3)?** |  |
| **Does the test documentation include information on the purpose of the test, the test equipment, the acceptance criteria and the test results (ISB 1263/MDD, Annex II, section 3.2 e); Annex V, section 3.2 (d) or ISB 1269/IVD, Annex II, section 3.2 e), Annex VII, section 3.2 (d))?** |  |
| **Is it ensured that only products fulfilling the Essential Requirements of ISB 1263/MDD, Annex I, or of ISB 1269/IVD, Annex I, will be released (ISB 1263/MDD, Annex II, section 3.2, 1st indent or ISB 1269/IVD, Annex IV, section 3.2, 1st indent)?** |  |
| 8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices |  |
| *Does the organization record (see 4.2.4) the identity of personnel performing any inspection or testing?* |  |

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| Control of nonconforming product | **Notes** |
| Does the organization ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery? |  |
| Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure? |  |
| *Does the organization deal with nonconforming product by one or more of the following ways:* |  |
| Where applicable, does the organization deal with nonconforming product by one or more of the following ways: |  |
| a) By taking action to eliminate the detected nonconformity? |  |
| b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer? |  |
| *b) By authorizing its use, release or acceptance under concession?* |  |
| c) By taking action to preclude its original intended use or application? |  |
| d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started? |  |
| *Does the organization ensure that nonconforming product is accepted by concession only if regulatory requirements are met?* |  |
| *Are records of the identity of the person(s) authorizing the concession maintained (see 4.2.4)?* |  |
| Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained (see 4.2.4)? |  |
| Is a nonconforming product, after its correction, subject to re-verification to demonstrate conformity to the requirements? |  |
| *When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity?* |  |
| *If product needs to be reworked (one or more times), does the organization document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction?* |  |
| *Prior to authorization and approval of the work instruction, has a determination of any adverse effect of the rework upon product been made and documented (see 4.2.3 and 7.5.1)?* |  |
| **Does the organization/manufacturer ensure that non-conforming product is accepted by concession only if all requirements of ISB 1263/MDD or of ISB 1269/IVD are met?** |  |

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| Analysis of data | **Notes** |
| Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made? |  |
| *Has the organization established documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made?* |  |
| Does this include data generated as a result of monitoring and measurement and from other relevant sources? |  |
| Analysis of data shall provide information relating to: |  |
| a) Customer satisfaction (see 8.2.1)? |  |
| *a) Feedback (see 8.2.1)?* |  |
| *b) Conformity to product requirements (see 7.2.1)?* |  |
| b) Conformity to product requirements (see 8.2.4)? |  |
| *c) Characteristics and trends of processes and products including opportunities for preventive action?* |  |
| c) Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4)? |  |
| *d) Suppliers?* |  |
| d) Suppliers (see 7.4)? |  |
| *Are records of the results of the analysis of data maintained (see 4.2.4)?* |  |

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| Improvement |

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| Continual improvement (ISO 9001:2008) | **Notes** |
| Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review? |  |

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| 8.5.1 General (ISO 13485:2003) | **Notes** |
| *Does the organization identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.* |  |
| *Has the organization established documented procedures for the issue and implementation of advisory notices?*  |  |
| *Are these procedures capable of being implemented at any time?* |  |
| *Are records of all customer complaint investigations maintained (see 4.2.4)?* |  |
| *If investigation determines that the activities outside the organization contributed to the customer complaint, has relevant information shall be exchanged between the organizations involved (see 4.1)?* |  |
| *If any customer complaint is not followed by corrective and/or preventive action, is the reason authorized (see 5.5.1) and recorded (see 4.2.4)?* |  |
| *If required by national or regional regulations, has the organization established documented procedures to notify the regulatory authorities of those adverse events, which meet the reporting criteria?**IAF MD09:Is the reporting of recalls & incidents performed in accordance with the requirements (timing, content, recipients)* |  |
| **Has procedures been implemented to ensure that :*** **The risk analysis is kept up to date based on feedback and active searches**
* **Clinical data is kept up to date**
* **The company complies with the established Post market surveillance plan/ Post market clinical follow up plan**
 |  |
| **Are the criteria for notification to authorities identified and described in accordance with ISB 1263/MDD, Annex II, section 3.1, 8th indent; Annex V, section 3.1, 8th indent; or Annex VI, section 3.1, 8th indent or with ISB 1269/IVD, Annex IV, section 3.1, 7th indent or Annex III, section 5)?** |  |
| **Note (MDD): Further reference is made to the official MEDDEV document 2.12/1 regarding "Guidelines on a Medical Devices Vigilance System” (hereafter GMDVS).** |  |
| **Have the relevant parties under a notification obligation been identified (or referred to) (Name, address and contact person of the National Competent Authorities of EU and Notified Bodies, ISB 1263/MDD, article 10 or ISB 1269/IVD, article 11)?** |  |
| **If applicable, does the organization/manufacturer ensure that the “Guidelines for Medical Device Vigilance System” are known to its authorized representative), per­sons responsible for placing devices on the market and any other agents authorized to act on its behalf for purposes related to vigilance (GMDVS, section 2.1.2)?** |  |
| **Has the organization/manufacturer established a procedure for the evaluation of incidents and for the decision process to determine which incidents should be reported to the National Competent Authorities of EU and the Notified Body (GMDVS, section 5)?** |  |
| **Does the procedure include time scale for notification to the National Competent Authorities and the Notified Body (GMDVS, section 5.6)?** |  |
| **Has the organization/manufacturer established a procedure for systematic recall/withdrawal of a device(s) from the marketplace (GMDVS, section 5.7)?** |  |
| **Does the procedure for systematic recall include an obligation to notify the National Competent Authorities of EU and the Notified Body (GMDVS, section 5.7)?** |  |
| **Do notification forms exist (GMDVS, Annex 3)?** |  |
| **Has the organization/manufacturer made the initiation, maintenance and monitoring of the system visible in those cases where an external party (e.g. a sales company) takes care of the actual market surveillance (GMDVS section 2.1.2)?** |  |

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| Corrective action | **Notes** |
| *Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence?* |  |
| Does the organization take action to eliminate the causes of nonconformities in order to prevent recurrence? |  |
| Are corrective actions appropriate to the effects of the nonconformities encountered? |  |
| Is a documented procedure established to define requirements for: |  |
| a) Reviewing nonconformities (including customer complaints)? |  |
| b) Determining the causes of nonconformities? |  |
| c) Evaluating the need for action to ensure that nonconformities do not recur? |  |
| d) Determining and implementing action needed? |  |
| *d) Determining and implementing action needed, including, if appropriate, updating documentation (see 4.2)?* |  |
| e) Records of the results of action taken (see 4.2.4)? |  |
| *e) Recording of the results of any investigation and of action taken (see 4.2.4), and* |  |
| f) Reviewing the effectiveness of the corrective action taken? |  |
| *f) Reviewing the corrective action taken and its effectiveness?* |  |

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| Preventive action | **Notes** |
| Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence? |  |
| Are preventive actions appropriate to the effects of the potential problems? |  |
| Is a documented procedure established to define requirements for: |  |
| a) Determining potential nonconformities and their causes? |  |
| b) Evaluating the need for action to prevent occurrence of nonconformities? |  |
| c) Determining and implementing action needed? |  |
| d) Records of the results of action taken (see 4.2.4)? |  |
| *d) Recording of the results of any investigations and of action taken (see 4.2.4), and* |  |
| e) Reviewing the effectiveness of the preventive action taken? |  |
| *e) Reviewing preventive action taken and its effectiveness?* |  |