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 Presafe)** |  |
| 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) | 🞏 Presafe 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 |
| 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 Presafe 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 Presafe reserves the right to change the checklist without further notice***

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

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**

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

**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 Presafe 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 Presafe to audit the subcontractor: |
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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? |  |
| **For Non EU Manufacturers: Has a contract been established between the manufacturer and a European representative (EUR)? The contract shall specify the obligations of the EUR and the manufacturer.** |  |
| *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?**The manual shall be in English, Danish, Swedish or Norwegian.****For Local units- Local language is ok** |  |
| *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?* |  |
| **The quality system shall include the regulatory requirements and standards (including revision level) for which the manufacturer complies.** **Specification of MDD/IVDD shall include Annex(es) used.** |  |
| **Has the organization/manufacturer implemented documented procedures for the preparation and control of the EC Declaration of Conformity in accordance with MDD/IVDD, including authority for signing** |  |
| **Have documented procedures been established for establishment and maintenance of Clinical data (MDD Annex X, section 1 and current MEDDEV. 2.7.1, “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| **Have documented procedures been established, where relevant, for the conduct and approval of clinical investigations (MDD article 15 & Annex X, Harmonized standards and MEDDEV. 2.7.1 “CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES”)?** |  |
| **Has a procedure for determining whether the device is medical device (As per MDD/IVDD) and for the classification of the device (for IVDD- weather the device is for self-test or belong to Annex II, list A or list B of the IVDD.** **The documented procedure shall include requirements for registration (Class, intended use, Rule used and justification for gray zone classifications)** |  |
| **A documented procedure for establishment and control of the technical file (as per MDD/IVDD) shall be established. The procedure shall include:*** **Listing of the elements of the technical file**
* **Organization of the file**

**The file shall be organized so that it is easy retrievable*****The file shall be in English, Danish, Swedish or Norwegian*** |  |
| **MDD** **Products containing ‘human blood derivative’:****Has a procedure ensuring that PS DK is informed of each batch of devices released and that the information includes the official certificate concerning the****release of the batch of human blood derivative (issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.** |  |
| **IVDD – devices in Annex II, List A****Batch Release:****Have procedures for the release of the devices , including requirements for testing of PS DK “provided panels”, communication of results to Presafe Denmark, release after PS DK approval etc., been implemented** |  |

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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 Presafe: Does the company destroy outdated versions of certificates issued by Presafe |  |
| *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 documented procedures exist ensure that relevant standards and regulatory requirements comes to the knowledge of the manufacturer. Are the relevant standards and regulatory documents available and controlled?****Is there a documented procedure in place for impact assessment of new standards/regulatory requirements?** |  |
| **Does the documented procedures require a documentation retention time of at least five years (15 years for implants) after the last product has been manufactured, as per the MDD/IVDD** |  |
| **Do documented procedures require are changes to the product and/or system documentation assessed for being in compliance with MDD/IVD. For devices this shall include compliance with Essential Requirements, the risk analysis and the clinical data?** |  |
| **Has the manufacturer implemented documented procedures to ensure that procedures are implemented for having a controlled list of devices carrying the CE0543 mark?****The list shall include Reference to EC certificate and for each device the type identifier [REF], 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 documented procedures specify requirement for notifying substantial changes of the product and/or Quality system documentation to the NB****The manufacturer must, in documented procedures, specify guidelines that interpret the “substantial” as it is applied to their company and devices** |  |

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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, being part of the technical documentation, for a period at least five years (15 years for implantable devices) after the last product has been manufactured** |  |

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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? |  |

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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).* |  |

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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)? |  |

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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?* |  |
| **Regulatory compliance aspects (e,g, Incident reports, recalls, Licenses/approvals, result from regulatory audits/external audits)**  |  |

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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? |  |
| **Conclusion on the compliance to the quality policy and regulatory requirements** |  |

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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 **(in documented procedures**): |  |
| *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? |  |
| **Determine competence requirements, for personal involved in regulatory requirements, include RA issues (e.g. Internal auditors, RA personnel, Risk management, Clinical evaluators)** |  |
| *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)? |  |

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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, been implemented?** |  |
| **Does quality planning reflect the requirements of the MDD/IVDD, the Essential requirements and relevant harmonized stands (e.g. For the establishment of documentation for the technical file, for implementing procedures, Inspections or tests as per requirements of MDD/IVDD, used standards and/or the essential requirements (And CTS for IVDD).** |  |
| 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 documented procedures implemented that ensures that only the following devices can be sold to EU/EFTA countries:*** **Devices that are CE marked and**
* **Devices where the language of the labelling reflects the requirement of the specific country to where the device is to be sold**

**The manufacturer must maintain evidence of control of language requirements within the countries where the device is sold.** |  |
| **In case of Distributor’s or external sales organization:****Are procedures in place for ensuring that contracts with these parties include relevant requirement such as:*** **Traceability**
* **Reporting complaints, post market feedback, incidents etc to the manufacturer – including time frames**
* **Participation in recall´s**
* **The Distributor’s or external sales org. shall be familiar with reporting requirements**
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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)?* |  |
| ***Does the process for control of arrangements for communicating with customer ensure that relevant personnel reviews the communication to ensure that claims is in accordance with the Intended use and indications as documented in the technical file*** |  |

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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 the planning include allocation of time and resources for MDD/IVDD (e.g. Establishment of technical file, verification/validation as per standards, Usability, clinical data and trials, Biocompatibility testing)**  |  |
| *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? |  |
| **Is there procedures to ensure that the essential requirements and relevant harmonized standards is used for identifying device requirements** |  |
| **Are language requirements, Specifically for CE countries, part of the design input** |  |

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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)? |  |

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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)? |  |
| **Does the verification document compliance to essential requirements and relevant harmonized standards, as identified in the design input** |  |

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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?* |  |
| **Are clinical evaluations and/or Clinical tests performed as per procedural requirements (see 4.2.2)** |  |
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| *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)? |  |
| **Procedures for review of the following, in relation to design changes, must be implemented:*** **Evaluation of impact of MDD compliance, including Risk analysis, clinical data and Essential requirements**
* **Evaluation of the need for reported to Presafe (There must be an interpretation of substantial changes, by the company, and it must be acceptable)?**

**The procedure must clarify which type of changes need approval by Presafe Denmark A/S. Examples are:*** **For class III – All design changes, except for layout changes to the manual**
* **New sterilization method or cycle**
* **For implantable devices, material change.**
* **For critical software, Software revision**
* **In case of increased risk**
* **In case of new intended use**
* **In case of new MD codes being applicable for the device**
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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)? |  |
| **Do the procedures include specific requirements for control of significant suppliers and subcontractors (outsourced processes).** **CE Marking: For these suppliers/subcontractors, where evidence of compliance is not documented at the manufacturer, the contracts hall include:*** **Presafe Denmark A/S has right to audit the supplier, including unannounced. The right shall cover the entire supply chain (incl. unannounced) until evidence of compliance can be identified.**
* **The manufacturer has right to audit the supplier**
* **Change control, Dispensations/Waivers/On-time-chages shall be covered**
* **Obligations, responsibilities and duties of the supplier/subcontractor (QS requirements, Standards, processes, right to approve)**
* **Certifications of the supplier/subcontractor**
* **Requirement for COC/COA**
* **Corporation in case of CAPA, Complaints, recalls and Incidents**
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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)?* |  |

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| Verification of purchased product or service | **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 documentation (e.g. test reports, COA/COC, calibration certificates, externally developed test protocols) verified for compliance to requirements, including the requirements of the MDD/IVDD, used standards and guidelines.?** |  |

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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, are requirements from MDD/IVDD, essential requirements & used standards included in the production process. E.g. Test of EO residuals, Cleaning of devices, specific production methods?** |  |
| 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** |  |

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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? (See section 7.2)** |  |
| 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.* |  |

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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 the MDD/IVDD and other implemented regulatory requirements** |  |
| **All areas within the Quality system should be audited minimum every 2nd year (significant/critical processes more frequent). Critical processes minimum annually.** |  |
| 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?* |  |
| **Does the testing and testing provide needed evidence of compliance to the MDD/IVDD, the Essential requirements, relevant standards (or parts of standards) and, specifically for the IVDD, the CTS.** |  |
| 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)?* |  |

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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 (New risks to be introduced, Consolidation of risks based on PMS)**
* **Clinical data is kept up to date (including method and frequency)**
* **Interval between the updates (risk & clinical) must be described**

**The above may be specified in device related post market plans** |  |
| **For companies with PMCF plans, are the plan followed** |  |
| **Has documented procedures been made for reporting of incidents with respect to the MDD/IVDD, including current MEDDEV on vigilance, been established?****The procedure shall minimum include:*** **Definition of incident and incident types (severity) (Including any interpretation as relevant to their devices.)**
* **Timeframe for reporting**
* **Process for reporting**
* **Templates to be used for reporting**
* **Criteria’s for which authorities to report to (also for incidents outside EU)**
* **Requirement for informing Presafe Denmark of any communication in relation to Incident reporting (All communication must go to Presafe DK at the same time as it is send to the authorities)**
 |  |
| **Procedure for FSCA must be implemented.** **The procedures shall include requirements in relation to authorities (as per MEDDEV 2.7.1), including:*** **Timeframe for reporting**
* **Process for reporting**
* **Criteria’s for which authorities to report to (also for incidents outside EU)**
* **Requirement for informing Presafe Denmark of any communication in relation to FSCA´s (All communication must go to Presafe DK at the same time as it is send to the authorities)**
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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?* |  |