[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR PRODUCTION AND SERVICE PROVISION

Commented [AES2]: Delete if the organization only deals with service provision.

Commented [AES3]: Delete if the organization doesn't provide services.

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES4]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES5]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to describe the process of production according to demanded quantity and deadlines, in line with the request for product quality, and the service provision process according to customer request.

The Procedure applies to the realization of the production and service process.

Users of this document are persons responsible for the process of production and service provision in [organization name].

2. Reference documents

- ISO 13485:2016 standard, clauses 7.1, 7.5
- ISO 14971:2019
- MDR 2017/745, article 10(9), Annex I – Chapter II, and Annex IX – Chapter I
- IVDR 2017/746
- Procedure for Document and Record Control
- Procedure for Human Resources
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Design and Development
- Warehousing Procedure
- Procedure for Control of Nonconforming Products
- Procedure for Corrective and Preventive Action
- Procedure for Equipment Maintenance and Measuring Equipment
- Procedure for Labeling
- Procedure for Identification and Traceability
- Procedure for Validation
- [Working instruction manuals]

Commented [AES6]: Delete if the organization only deals with service provision.

Commented [AES7]: Delete if the organization doesn't provide services.

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Commented [AES9]: Delete if the organization doesn't provide services.

Commented [AES10]: Delete if the organization only deals with service provision.

Commented [AES11]: Delete if the organization doesn't provide services.

Commented [AES12]: Include the name of your organization.

Commented [AES13]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

Commented [AES14]: Delete this if you do not have a certified in vitro diagnostic medical device

Commented [AES15]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "00_Document_Management".

Commented [AES16]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "05_Human_Resources".

Commented [AES17]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit folder "11_Purchasing_and_Evaluation_of_Suppliers".

Commented [AES18]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "10_Design_and_Development".

Commented [AES19]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "17_Warehousing".

Commented [AES20]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "18_Nonconformities".

Commented [AES21]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25_Corrective_and_Preventive_Action".

Commented [AES22]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "20_Equipment_Maintenance".

Commented [AES23]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "13_Identification_and_Labeling".

Commented [AES24]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "13_Identification_and_Labeling".

Commented [AES25]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "15_Validation".

Commented [AES26]: List the names of instruction manuals used in this process.

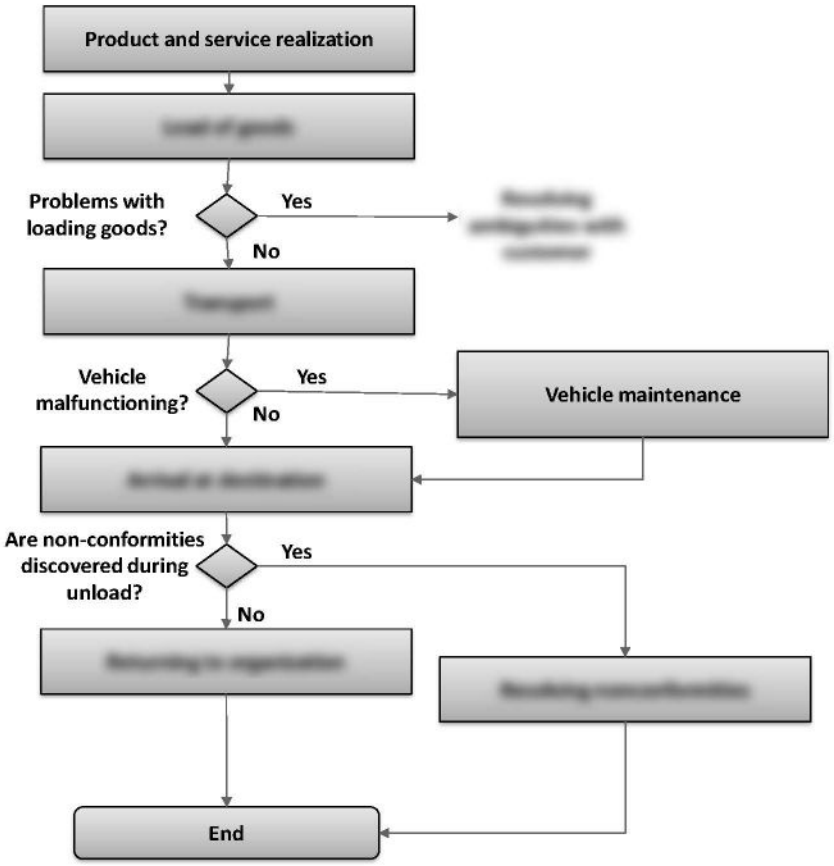
3. Product and service realization

3.1. Process flow

Commented [AES27]: Delete if the organization only deals

Commented [AES28]: Delete if the organization doesn't

Commented [AES29]: This is only an example of a process flow



3.2. Product and service realization planning

3.2.1. Defining resources for production and service provision

According to [document name], [job title] makes an internal purchasing order that specifies quantities of raw material and other resources needed for realization of product or phase, defined in the Project Plan, and delivers it to [job title]. [illegible] defines which working instructions will be applied during product realization. Quality objectives, requests for product, and criteria for accepting product are stated in the Product Specification made by [illegible]. Also, [illegible] must ensure that product requirements are compliant with external standards and applicable legal and regulatory requirements.

[Job title] creates the Quality Plan, which defines necessary activities of verification, monitoring, measuring, controlling, and testing the product.

3.2.2. Product realization planning and risks and analysis

This phase includes, as applicable:

- [Job title] defines and evaluates manufacturing operations and processes.
- [Job title] develops adequate and capable processes.
- [Job title] must ensure identification of special processes and consideration of associated risks and consequences.
- [illegible] must ensure establishment and implementation of appropriate process control measures.
- [illegible] must ensure development of instructions and training for process operators.
- [illegible] must prepare requirements necessary to demonstrate process conformity.

[Job title] maintains evidence of risk management activities in the product realization process. This process should include the following elements: risk plan, risk analysis, risk management report, and production and post-production information. This process is carried out according to the [illegible] for Risk Management.

3.2.3. Product verification and validation planning

[Job title] must conduct validation of all processes of production and service provision where:

- It is not possible to confirm by measurement that a product or service satisfies customer request.
- It is not possible to conduct measurements, because the product or service is being destroyed in the process.

Where appropriate, as part of validation, [job title] must determine:

- Criteria for the review and approval of the process
- Equipment and personnel qualifications needed for process execution
- Special working instructions

Commented [AES30]: E.g., Production Plan, Customer [illegible]

Commented [AES31]: E.g., Production Manager

Commented [AES32]: E.g., Warehousing Manager

Commented [AES33]: E.g., Production Manager

Commented [AES34]: E.g., Production Manager

Commented [AES35]: E.g., Production Manager

Commented [AES36]: E.g., Production Manager

Commented [AES37]: E.g., Production Manager

Commented [AES38]: E.g., Production Manager

Commented [AES39]: E.g., R&D Manager

Commented [AES40]: E.g., Production Manager

Commented [AES41]: E.g., Production Manager

Commented [AES42]: E.g., R&D Manager

Commented [AES43]: E.g., R&D Manager

Commented [AES44]: You can find a template for this [illegible]

Commented [AES45]: E.g., Production Manager, QA Manager

Commented [AES46]: For example, lacquer thickness of [illegible]

Commented [AES47]: E.g., Welding – techniques for testing [illegible]

Commented [AES48]: This is entered to Quality Plan.

- Records needed to provide evidence of controlling parameter
- [illegible]

[Job title] creates records of product/service conformance needed to provide evidence that realization processes and resulting products meet predefined requests.

[illegible]

[Job title] defines the program of inspection and testing activities to be conducted within the verification and validation of the product, and the materials and components that constitute the product. This includes the following:

- Defining points in the production process where inspection and testing will be conducted
- Defining the scope of inspection and testing activities, as well as the scope, frequency, and methods to be used
- [illegible]
- [illegible]

3.2.4. Identification and traceability

[Job title] must identify the product through the entire production process according to the Procedure for Identification and Traceability, and define the methods of identification and enter them in the Record of Product/Service Conformance. Identification is equally applicable for raw material, semi-finished, and final products.

[illegible]

3.3. Production and service provision realization

Production is executed in controlled working conditions, which implies compliance with all technical and technological requirements defined in the documentation necessary for the production process. If any violation or nonconformance of any working condition occurs, [job title] is obliged to stop the production process until the reestablishment of all proper working conditions.

[illegible]

The production process, when it is applicable, must be followed by a record, which will include the following: when production started, based on which order or work order, lot of batch, individual steps of production, who made them, on what equipment, who checked, and who eventually approved production and that everything went through well. [illegible]

3.3.1. Availability of information that defines product or service characteristics

In cyclic production, [job title] gathers information about product characteristics from the following sources: [name the sources].

Commented [AES49]: This is entered to Quality Plan.

Commented [AES50]: Adapt to the organization's needs.

Commented [AES51]: This is done when previous validation [illegible]

Commented [AES52]: E.g., Production Manager, QA Manager

Commented [AES53]: E.g., Production Manager, QA Manager, [illegible]

Commented [AES54]: E.g., Production Manager, QA Manager

Commented [AES55]: E.g., serial number, working order ID, [illegible]

Commented [AES56]: E.g., Production Manager, QA Manager

Commented [AES57]: Depending on organization's practices lot number can be constructed by software or manual.

[illegible]

Commented [AES58]: This refers to legal and regulatory requirements.

Commented [AES59]: E.g., Production Manager, Quality Manager

Commented [AES60]: E.g., Production Manager, Quality Manager

Commented [AES61]: E.g., Product Specification, legal and [illegible]

Commented [AES62]: Delete if there is no cyclic production.

[For project-based production and individual production according to customer request, information about product characteristics is defined in [document name].]

Commented [AES63]: E.g., Customer Request, Project Task, etc.

3.3.2. *Availability of working instructions*

Commented [AES64]: Delete if the organization doesn't [...]

[Job title] is responsible for the creation of all working instructions for the following process activities: [list the names of working instructions for each activity].

Commented [AES65]: E.g., Production Manager

Commented [AES66]: Working instructions are needed for [...]

3.3.3. *Installation activities*

Commented [AES67]: You can delete this section if your [...]

[Job title] is responsible for the installation of the medical device and verification of acceptance criteria for installation. If necessary, top management can decide to outsource the installation of the medical device to another company. [In such case, [job title] must prepare a contract for the provision of installation services. [Job title] is responsible for conducting and maintaining the Record of Medical Device Installation.]

Commented [AES68]: E.g., Production Manager, Installation [...]

Commented [AES69]: You can delete this sentence if your [...]

3.3.4. *Service activities*

Commented [AES70]: E.g., Production Manager, Installation [...]

Commented [AES71]: You can delete this section if your [...]

[Job title] is responsible for servicing the medical device. Top management is responsible for ensuring that necessary reference materials and reference measurements for performing servicing activities are available.

Commented [AES72]: E.g., Production Manager, Service [...]

[Job title] is responsible for conducting and maintaining the Records of servicing Activities, and to analyze if service information needs to be handled as a complaint. Where appropriate, results of the analysis can be inputs to the improvement process.

Commented [AES73]: E.g., Production Manager, Service [...]

3.3.5. *Usage of adequate equipment*

Commented [AES74]: E.g., Maintenance Operator

[Job title] is responsible for ensuring that all equipment is in operational condition and, per [job title]'s request, delivers evidence of execution of the Plan for Preventive Equipment Maintenance and records of calibration and repairs of measuring equipment.

Commented [AES75]: E.g., Production Manager

Commented [AES76]: You can find a template for this [...]

If requirements for equipment maintenance and working environment are specified by the customer or legal and regulatory requirements, [job title] is responsible for complying with such requirements.

Commented [AES77]: E.g., Head of maintenance department

3.3.6. *Customer property*

Commented [AES78]: This can be deleted if the organization [...]

[Job title] is responsible for the identification, verification, and protection of customer property that is given for use or implementation in the product or service. [If customer property is lost, damaged, or in some other way unfit for use, [job title] notifies the property owner using Notification to a Customer about Changes on Property.]

Commented [AES79]: E.g., Production Manager, Warehousing Manager

3.3.7. *Conducting measuring and monitoring*

Commented [AES80]: E.g., Production Manager, Technology Engineer, etc.

[Job title] must define the method of the monitoring process of the product, and methods of sampling and measuring, and enter them into the Quality Plan.

Commented [AES81]: Other records can be defined in addition [...]

3.3.8. *Product acceptance, delivery, and activities after delivery*

[Job title] is responsible for determining by which degree the product requirements are met regarding Product Specifications and customer requirements. If requirements are met, [job title] confirms fulfillment of the requirements by signing [name of document] and approving shipment. [illegible]

Commented [AES82]: E.g., Production Manager, QA Manager

Commented [AES83]: E.g., Working order

[Job title] defines the following aspects regarding activities after product delivery:

- Planning servicing activities
- Need for competence of employees and training needs
- [illegible]
- [illegible]

Commented [AES84]: Adapt to the organization's needs.

During servicing activities, [job title] is obligated to initiate any necessary corrections of nonconformance using the Procedure for Control of Nonconforming Products for every nonconformity of products or services. [illegible]

Commented [AES85]: E.g., Production Manager, Maintenance Manager

3.3.9. Identification and traceability of product and process

[Job title] must identify the product through the entire production process and define methods of identification and enter them in the Record of Traceability. Traceability includes records of components, materials, and conditions for the work environment used.

Commented [AES86]: E.g., Production Manager

Commented [AES87]: Adapt to the organization's needs. [illegible]

[illegible]

Commented [AES88]: Delete if these do not cause failure of [illegible]

Commented [AES89]: E.g., Warehousing Manager, QA [illegible]

3.4. Product preservation

Commented [AES90]: Delete this section if the organization is [illegible]

[Job title] is responsible for preservation of product during the lifecycle of product and/or assembly parts.

Commented [AES91]: E.g., Production Manager

[illegible]

Commented [AES92]: E.g., Warehousing Manager

[Job title] is responsible for preservation of product during transport.

Commented [AES93]: E.g., driver

3.5. Resolving nonconformities

If a nonconformity of any process or product occurs, the person who discovered the nonconformity notifies [job title], who acts according to the Procedure for Control of Nonconforming Products.

Commented [AES94]: E.g., Production Manager, QA Manager

[illegible]

Commented [AES95]: E.g., shift leader

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		[illegible]	[illegible]	[illegible]	
Product Specification	PR12.1	[illegible]	[illegible]	[illegible]	[illegible]
Record of Product/Service Conformance	PR12.2	[illegible]	[illegible]	[illegible]	[illegible]
Quality Plan	PR12.3	[illegible]	[illegible]	[illegible]	[illegible]
Notification to a Customer about Changes on Property	PR12.4	2 years	[illegible]	[illegible]	[illegible]
Record of Production Process Validation	PR12.5	2 years	[illegible]	[illegible]	[illegible]
Record of Medical Device Installation	PR12.6	2 years	[illegible]	[illegible]	[illegible]
Record of Servicing Activities	PR12.7	2 years	[illegible]	[illegible]	[illegible]

Commented [AES97]: Adapt the information is this column to [illegible]

Commented [AES96]: Adapt the information is this column to [illegible]

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Commented [AES99]: If the record is in electronic form, write [illegible]

Commented [AES100]: If the record is in electronic form, [illegible]

Commented [AES101]: If the record is in electronic form, [illegible]

Commented [AES102]: If the record is in electronic form, [illegible]

Commented [AES103]: If the record is in electronic form, [illegible]

Commented [AES104]: If the record is in electronic form, [illegible]

5. Appendices

- Appendix 1 – Product Specification
- Appendix 2 – Record of Product/Service Conformance
- Appendix 3 – Quality Plan
- Appendix 4 – Notification to a Customer about Changes on Property
- [illegible]
- [illegible]
- [illegible]

[job title]
[name]

[signature]

Commented [AES105]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.