[Organization logo]

[Organization name]

SALES PROCEDURE

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

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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 all activities related to the sales process, from recording the customer's requests to delivery of product and service.

2. Reference documents

- ISO 13485:2016 standard, clauses 7.2.1, 7.2.2, and 7.2.3
- MDR 2017/745, article 10(9)
- Procedure for Production and Service Provision
- Quality Manual

Commented [AES4]: 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 [AES5]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "12_Production_and_Service_Provision".

Commented [AES6]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

3. Sales process

3.1. Process flow
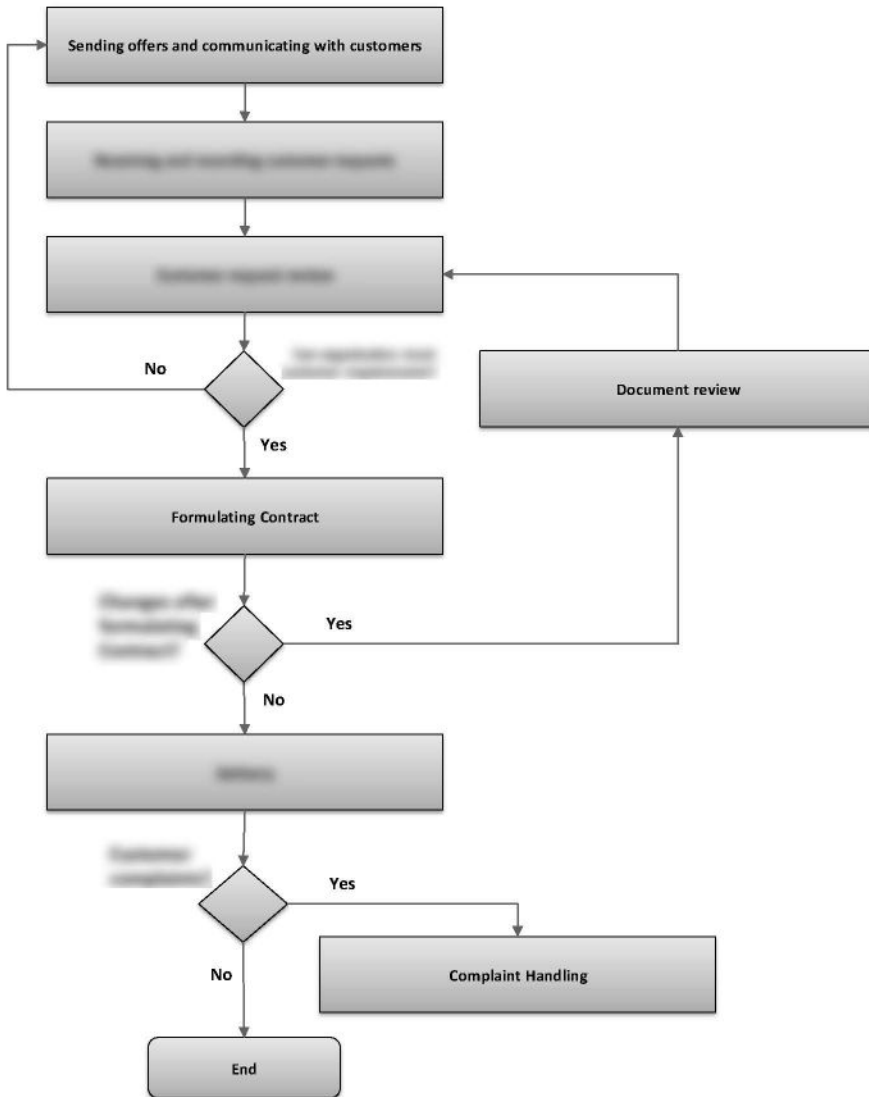
3.2. Sending offers and communication with customers

[Job title] notifies known customers about product they are interested in or delivers offer to ~~potential and new customers by representing to them a product or service~~ **through the** ~~organization's website, phone calls, flyers, posters, etc.~~

3.3. Receiving and recording customer's requests

[Job title] receives the customer's requests, and evaluates completeness and definition of requests. With a potential customer, [job title] clarifies potential ambiguities. ~~Determining requirements for product includes customer-specified requests as well as requirements that the customer didn't state, but are implied by intended use and legal requirements. [Job title] defines all necessary activities after shipment of the product.~~

If the customer changes its requests after signing a contract, [job title] treats changed requests as new requests and notifies [job title].

3.4. Customer's requests review

3.4.1. Customer's request review for product and services from regular assortment

[Job title] consults [job title] regarding whether requested quantity of product or service can be delivered within demanded deadline and notifies customer about possibilities of accepting a request. [Job title] checks stock status of ordered product and, if necessary, issues [name of document] to provide ordered quantity of product.

~~[Job title] analyzes all requirements that are not stated by the customer, but are necessary for specified or intended use and applicable regulatory requirements related to the product.~~

~~[Job title] confirms the customer's request by signing the [document] received by the customer and filling in Product Requirements Review Record.~~

3.4.2. Customer's request review for **non-standard product and services** and **individual production**

Non-standard product (service) is any product (service) which differs from the regular assortment of the organization regarding size, package, ingredients, weights, etc.

~~Individual production means that the organization produces one single product for one single customer according to the project provided by the customer.~~

[Job title] records such requests in the Customer Requirement Review Checklist, and [job title] analyzes it in order to determine necessary actions to meet the customer's request.

If the customer's request cannot be met, [job title] informs the customer about the inability to meet the request.

~~If the organization is able to meet the customer's request, [job title] informs the customer and makes an offer. In the case of individual production, the customer delivers the project with all specified requests to [job title].~~

[job title] communicates with customers related to accepting the offer. [job title] decides whether the additional requirements of the customer will be met.

3.5. Formulating the contract

After reviewing the customer's requests and accepting an offer, [job title] creates the contract for delivering product or service. The contract must contain all customer requests, activities after delivering product and way of solving customer's complaints.

If the contract or customer's order contains requests that differ from those previously stated, [job title] undertakes actions described in section 3.3 and, if the request can be met, contacts the customer in order to adjust the contract and appropriate documents to the customer's requests.

After adjusting to changes, [job title] prepares a new contract or annex and [job title] issues new [name of document] and delivery documents.

3.6. Creating delivery documents

[Job title] creates appropriate delivery documents based on reviewed customer requests and delivers them to [job title]. If delivery includes exporting to another country, [job title] makes necessary documents and, if necessary, hires an organization for handling freightage and/or customs clearance.

3.7. Product delivery and service realization

According to delivery documents, [job title] organizes loading of product. Delivery is made by organization's transport or outsourced transport. Transporter must provide necessary conditions in order to prevent spoiling or damaging of product or package.

After signing a contract, the organization starts with realization of service according to the contract.

If needed, [job title] prepares and performs user training for the medical device. These trainings are necessary to ensure safe product use.

3.8. Customer complaints

[Job title] is responsible for complaints from customers. All customer complaints are managed according to Procedure for Customer Communications, Feedback and Complaints.

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Product Requirement Review Record	PR08.1	2 years	Office of the Sales Manager	Records are stored in the cabinet	[job title]

5. Appendices

- Appendix 1 – Product Requirement Review Record

[job title]
[name]

_____
[signature]

> **Commented [AES47]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.