Management Review Report

# Meta information

## Purpose

## Addressees

## Evaluation period

## Participants

# Input for management review

## Business development

### Corporate environment

### SWOT

### Strategy

### Growth

### Focus of corporate activity

## Quality objectives & Quality policy

### Overview

### Objectives we have achieved

**2.2.3 Objectives that we have not achieved or have only partially achieved**

## Monitoring and measurement of processes and products

### Evaluation of the key performance indicators

### Status of risk management

### Field A

### Field B

## Feedback & product problems

### Feedback from the market / customer satisfaction

### Field A

### Field B

### Complaint handling

### Reporting to regulatory authorities (z.B. Incidents, Recalls)

## Results of internal and external audits

### External Audits

### Internal Audits

## Status of the implementation of measures

### Implementation of recommendations

### Implementation of follow-up measures of previous management reviews

### Implementation of other corrections, corrective actions and preventive actions

## Relevant changes

### Internal und external changens

### New & changed regulatory requirements

# Summary & Decisions

## Result of the review

## Recommended measures & improvements

## Adaptation of quality policy & quality objectives

# Annex

Note: A complete template for a management review with an example and instructions for completion can be found in the Auditgarant (www.auditgarant.de).

In the Auditgarant, Johner Institute auditors and consultants provide you with a complete set of templates for both the quality management system and your technical documentation.

This helps you to quickly and conveniently meet the regulatory requirements and to be allowed to market your medical device.