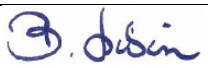
QUALITY MANAGEMENT MANUAL

		Signature	Date
Author:	R.A. Thieme Groen		01-02-2018
Released Management	Prof. Dr.med. Dr.h.c. B. Arabin		10-07-2018

Revision	Date	Description of the change	QMB	GL
1.0	01-02-2018	First version		
2.0 3.0	10-07-2018 (BA) 30-07-2019 (BA)	Notes on other applicable documents added Control element: FB 4.0-01 Chapter Design & Development added		

Dr. Arabin GmbH & Co KG
Alfred-Herrhausen-Strasse 44
58455 Witten
info@ dr-arabin.com
+49 (0)2302-189214

Content

1. Introduction

This Quality Management Manual (QMH) describes the quality management system (QM system) of Dr. Arabin GmbH & Co KG. The QM system was established based on the requirements of DIN EN ISO 13485 "Medical Devices - Quality Management Systems - Requirements for regulatory purposes" in its current version, as Dr. Arabin manufactures and distributes pessaries for urogynaecology and obstetrics. The QMH, which is based on the structure of this international standard, describes all quality-relevant processes and responsibilities within the company. This is intended to achieve a uniform understanding of the QM system at all levels of the company.

2. Company information

Dr. Arabin GmbH & Co KG was founded by the gynaecologist Dr. Hans Arabin in Siegen in 1967. He developed various models of pessaries "at home", initially for the treatment of problems with sagging, later on for the treatment of patients with imminent premature birth. His daughter Prof. Birgit Arabin took over the management of the company in 1997. She decided to locate the company in Witten and to move the major part of production to a workshop for the disabled. Increasingly, work processes in both production and sales have been standardised, automated and certified. In 2012, an additional training centre (Villa Clara Angela) was acquired in Berlin, where training courses on pessary therapy can be held and studies coordinated.
The basic principle of the company is not only economic advantage but also the development of clinical and scientific fundamentals. Profits of Dr. Arabin GmbH & Co KG go to the Clara Angela Foundation, founded in 1997 by Prof. Birgit Arabin (www.clara-angela.info). Independently of this, cooperation with uro-gynaecologists is being intensified in order to stimulate studies and develop new models in this area as well.

Address

Company:	Dr Arabin GmbH & Co KG
Address	Alfred Herrhaussen Strasse 44 D-48544 Witten
website	www. dr-arabin. de
Phone	+49 (0)2302-189214
E-mail	info@dr-arabin.de

3. Range of services of Dr. Arabin GmbH & Co KG

The Dr. Arabin GmbH & Co KG has many years of experience in the manufacture, distribution and final testing of pessaries in the urogynaecological and obstetrical field. The following products are offered:

GYNAECOLOGY
Adjustment set
Incontinence
Urethra Pessary, Urethra Bowls Pessary
Treatment of genital prolapse
Ring Pessary, Thick Ring, Sieve Bowl Pessary, Bowl Pessary, Hodge Pessary, Club Pessary
Cube pessary with button perforated and unperforated, Tandem pessary perforated and unperforated
Anatomical features
vaginal dilator

OBSTETRICS
Cerclage Pessary perforated/unperforated

SPECIALIST MEDICAL ADVICEs ON REQUEST ALSO FOR CUSTOMIZED PESSARIES

4. Quality management system

4.1 General requirements

The quality management system of Dr. Arabin GmbH & Co KG operates according to the standard **DIN EN ISO 13485 in all areas of the company.**

Dr. Arabin GmbH & Co KG, as manufacturer and sales organisation of pessaries, has introduced, documented and implemented a QM system in accordance with DIN EN ISO 13485 and the applicable regulatory requirements and undertakes to maintain it effectively.
The processes and necessary validations required for the QM system and its application throughout the entire organization were identified and the interactions were defined accordingly. These processes are managed using a risk-based approach.

4.1.2 Outsourced processes

The processes of **manufacturing** and **further processing of** individual products are outsourced in our company. The outsourced processes have been defined; the type and scope of monitoring depends on the complexity and risks involved, with the responsibility resting with our company. These processes are described in more detail in the production documents, procurement, supplier audits and test protocols. The **monitoring of the processes** is carried out by means of a systematic incoming goods department and visual inspections of each product. When processes are outsourced, compliance with standard requirements and regulatory requirements is checked.

Other applicable SOPs
SOP 07.5.1-01 Control of production

4.1.3 Validation of software

Computer software that falls within the scope of the QM system of Dr. Arabin GmbH & Co KG must be validated. The specific activities related to software validation and revalidation (following changes to this software or its application) depend on the risk associated with the use of the software.

Other applicable SOP

SOP 04.1.3-01 Validation of software used in Q processes

4.2 Documentation requirements

4.2.1 General information

The documentation of the QM system of Dr. Arabin GmbH & Co KG follows the structure of DIN EN ISO 13485, with the QM system being hierarchically structured, with the QM manual being the main document. This describes the entire QM system of Dr. Arabin GmbH & Co KG. The following documents serve to maintain the QM system:

- Procedural instructions
- Forms/ work instructions / records / medical device files

4.2.2 Quality management manual (QMH)

This quality management manual is subject to an annual audit. The manual exists in a central digital and written form, i.e. one edition of the manual is located in the company's internal network, another written version in the company's office. This presentation of the manual promises a version-conflict-free handling, easy updating and is accessible for every employee from every area of our company.
The QMH describes the scope of application of the QM system of Dr. Arabin GmbH & Co KG and represents the superordinate document of the entire QM system of the company.

The interactions of the processes of the QM system, i.e. the procedures, are described in the manual and in associated procedural instructions. Applicable procedure instructions and forms or work instructions can be taken from the "Annex QM Manual: Form Approved Documentation for the QM System", which is intended to provide an overview and control element without having to correct basic procedures too often.

Non-applicable standard requirements (justification in the respective chapter) after 13485-2016

7.5.3 Activities during installation
7.5.4 Maintenance activities
7.5.5 Special requirements for sterile medical devices
7.5.7 Special requirements for validation of sterilization processes & sterile barrier systems
7.5.9.2 Special requirements for implementable medical devices

Exclusions

Prior to 2019, we did not carry out any development Standard exclusion of→ point 7.3, from 2019 onwards we have used the experience gained during the company's existence as well as new technical and clinical findings to continuously improve our products and plan new developments.

4.2.3 Medical device file

For each type or group of medical devices we have created a file (medical device file, technical file) which is updated. It contains the regulatory requirements described or a reference to them. The file either contains the information or refers to its location.

The medical device file contains:

- A general description of the product
- The intended use / the intended purpose
- The unique identification/label or label (sample without batch or size)
- The instruction manual (current form with revision status offline/online)
- The detailed product specifications
- Processes / procedures and specifications for
    - Production
    - Further processing
    - Packaging
    - Storage
    - Distribution
- Processes / procedures for measurement and monitoring

4.2.4 Control of documents

All quality-relevant documents of the QM system are subject to document control to ensure that only checked and approved (internal/external) documents are used within the company. The associated process instruction describes and records all control measures required by DIN EN ISO 13485 as well as the necessary applicable regulatory requirements.

4.2.5 Control of records

Quality relevant records are also subject to document control. The associated procedural instructions define the necessary control measures for records (identification, retention, protection of confidential information, retrievability, retention period).

Other applicable SOP

SOP 04.2-01 Control of documents and records

5. Management responsibility

5.1 Management commitment

The management develops the quality management system with the help of the quality management representatives and the other employees. Furthermore, the management is obliged to monitor the effectiveness and improvement of the quality management system and to ensure that specifications and rules, especially with regard to customer requirements as well as legal and official requirements, are sufficiently known to the employees and are taken into account in the fulfilment of the tasks.

5.2 Customer orientation

Customer satisfaction determines the success of the Dr. Arabin GmbH & Co KG company. Our company is designed to answer customer inquiries as quickly and completely as possible and to complete orders within the agreed time frame. As part of our company philosophy, Dr. Arabin GmbH & Co KG wants to achieve comprehensive customer satisfaction and thus long-term customer loyalty. Management ensures that customer requirements and applicable regulatory requirements are identified and met.

5.3 Quality policy

The top management defines the quality policy and carries out a management evaluation at regular intervals to ensure the implementation, realisation and effectiveness of the QM system.

5.4 Planning

5.4.1 Quality objectives

The quality targets are set by the top management of Dr. Arabin GmbH & Co KG. They are measurable and are in line with the quality policy. The fulfilment and appropriateness of the quality objectives are evaluated during the annual management review and documented accordingly. Should it be determined that the quality objectives no longer meet current requirements, the management will update the quality objectives.

5.4.2 Planning of the quality management system

The QM system is planned by the management in cooperation with the QMB. Within the scope of this function, the processes required for the fulfilment of the quality objectives and their application in the company as well as their interaction are identified and defined.

In order to ensure its functionality, the QM system including its documents (QMH, process or procedural instructions, forms) is checked at regular intervals to ensure that it is effective and up-to-date. Necessary changes are incorporated into the QM system accordingly, according to a risk-based approach.

Other applicable SOP
SOP-07.1-02 Change management

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The corporate structure of Dr. Arabin GmbH & Co KG is shown in an organizational chart. The positions and associated areas of responsibility of the individual employees can be seen in the function matrix. In the case of a new position, a position description must first be drawn up by the management. Furthermore, responsibilities and competencies are also described directly in the procedural instructions.

5.5.2 Quality Management Representative(s) (QMB)

The management appoints the Quality Management Representative (QMB) and ensures that this person has the necessary competencies and resources to fulfil the tasks. The QMB has the responsibility and authority to

(a) ensure that the processes required by the quality management system are documented
(b) report to senior management on the effectiveness of the quality management system and any need for improvement;
(c) ensure the promotion of awareness of applicable regulatory and quality management system requirements throughout the organisation.

5.5.3 Internal communication

The management ensures that appropriate processes of communication have been introduced within Dr. Arabin GmbH & Co KG and that there is communication about the effectiveness of the QM system. Daily stand-up meetings (daily meetings) and monthly team meetings serve this purpose, whereby "input" and "output" are checked against to-do lists.

5.6 Management assessment

5.6.1 General information

The management evaluation is carried out at least once a year to ensure the continued suitability, appropriateness and effectiveness of the QM system of Dr. Arabin GmbH & Co KG. This evaluation shall include an assessment of opportunities for improvement and the need for change, including the quality policy and quality objectives. If a requirement is not met, either a reasoned statement can be prepared and documented or corrective and preventive action can be taken.

5.6.2 Input for the evaluation

The inputs to the management review shall include, but are not limited to, information based on the following

(a) feedback;
b) Complaint processing;
(c) reporting to regulatory authorities;
(d) audits;
(e) monitoring and measurement of processes;
(f) monitoring and measurement of products;
(g) corrective actions;
(h) preventive measures;
(i) follow-up of previous management assessments;
j) Changes that could affect the quality management system;
(k) recommendations for improvements;
(l) applicable new or revised regulatory requirements.

5.6.3 Results of the evaluation

The results of the management assessment must include the inputs assessed and any decisions and actions taken concerning

(a) improvements necessary to maintain the suitability, adequacy and effectiveness of the quality management system and its processes
(b) product improvement in relation to customer requirements;
(c) changes required to respond to applicable new or revised regulatory requirements;
(d) resource requirements.

Other applicable SOP

SOP 05.6.-01 Management evaluation

6. Management and resources

6.1 Provision of resources

The management identifies and provides the resources required to implement and maintain the effectiveness of the QM system and to meet regulatory and customer requirements.

6.2 Human resources

The management of Dr. Arabin GmbH & Co KG ensures, with the help of job descriptions, that employees carry out activities that benefit product quality. Competences should be developed through:

- Education, training,
- Promotion of skills and
- Experience due to long-term employment.

Training is provided to achieve and maintain skills. Training measures are assessed according to their effectiveness. The staff is informed about the importance of their own activities and their contribution to the achievement of the quality objectives.

Documentation / quality records

Training records (confirmation, attendance records, plans) are kept of all internal and external training courses, with the subject, date and participants being visible.

Other applicable SOP

SOP 06.2-01 Trainings

6.3 Infrastructure

The necessary infrastructure is recorded, documented and provided by the management. The company provides the infrastructure required for quality control, packaging and distribution of the products.

Documentation of the infrastructure

- Buildings, areas, workplaces and utilities are displayed,
- Lists of the machines with planned maintenance intervals are listed,
- Support services exist for transport, communication and information systems.

Maintenance activities

- Maintenance activities are carried out on all machines and equipment that have an influence on product quality.
- Maintenance intervals are listed and evaluated.
- Records are kept by the department.

Data backup

Our EDP data is regularly backed up by an external provider by means of mirroring.

6.4 Working environment and control of contamination

The management and the quality management officer help to design and maintain the working environment necessary to achieve conformity with the product and service requirements. Documented requirements for the control of contamination are in place.

Other applicable SOPs
SOP 06.3-01 Maintenance plan
SOP 06.4-01 Handling contaminated products

7. Product realisation

7.1 Planning the product realization

Dr. Arabin GmbH & Co. KG plans and develops all necessary processes in order to carry out the realization of medical devices and, if applicable, related services in compliance with the implemented quality management system. The established risk management process is applied in all phases of product realization.
The development of new or modified products will be included in the scope of the quality management system of Dr. Arabin GmbH & Co KG from 2019 onwards, in order to be able to continuously implement technical and clinical findings in the sense of product improvement in the interest of patients.

7.1.1 Risk management

Dr. Arabin GmbH & Co. KG has developed documented requirements for risk management activities based on EN ISO 14971 in its currently valid version during the entire planning of product realization. This ensures that any risks arising from production are avoided. New products or services must always be reviewed using risk management.

Other applicable SOPs
SOP 07.1-02 Risk management
SOP 07.1-02 Change management

7.2 Customer-related processes

7.2.1 Identification of the requirements related to the product

Within the scope of the sales activities of Dr. Arabin GmbH & Co KG, the determination and recording of customer requirements takes place. This ensures that customer requirements for the product are fully identified, including requirements for availability, delivery, support and additional other requirements. Requirements not specified by the customer for the intended use are also determined in this way.

7.2.2 Assessment of requirements related to the product

Before submitting an offer, accepting a contract or an order from our customers, the sales department of Dr. Arabin GmbH & Co KG determines and evaluates the requirements regarding the product. The ratings are recorded by the sales department. If there are no written requirements, this must be clarified with customers in advance and a note made if necessary.
In the event of deviations or contradictions between the requirements specified in the order/offer (possibly also from previous contractual relationships), these must be clarified with the customer in advance and recorded. Contract changes always lead to a new contract review with definition of the changed conditions. All relevant bodies are informed about changes in the contract.

7.2.3 Communication

The communication with customers and users takes place through direct or indirect communication e.g. through product information, inquiries, orders, commissions or order changes.
Feedback from customers is also of interest in the form of complaints, which are recorded and processed by the corrective and preventive action procedures. Any communication of recommended measures to our customers and communication with the regulatory authorities is ensured via the established vigilance procedure.
The results and evaluation of previous and clinical studies, as presented in the clinical evaluation, are accessible and communicable to clients and stakeholders at any time.

Other applicable SOPs
SOP 08.2.1-01 Feedback and complaints
SOP 07.2-01 Clinical evaluation

7.3 Development

7.3.1 General information

The process for development and development change was included in the scope of the quality management system of Dr. Arabin GmbH & Co KG from 2019. The aim of this was to leave the previously existing conformity assessment procedure according to Annex VI of Directive 93/42/EEC and to seek certification according to Directive 93/42/EEC Annex II, which continues to provide for a quality assurance system for the final inspection of products. All products of Dr. Arabin GmbH & Co KG are subject to this procedure.

7.3.2 Development planning

Dr. Arabin GmbH & Co KG plans and directs new developments of its products from 2018/2019 onwards. Development planning documents are maintained and updated during development. In the development planning, Dr. Arabin GmbH & Co KG documents
(a) the development phases;
(b) the evaluation(s) needed at each stage of development;)
(c) the verification, validation and design transfer activities for the development phases
(d) the responsibilities and authorities for development;
(e) the procedures for ensuring the traceability of development results
(t) the necessary resources, including the necessary competence of staff.

7.3.3 Development inputs

Inputs related to product requirements shall be identified and records maintained. These entries must contain
(a) functional, performance and suitability for use requirements as specified
(b) applicable regulatory requirements and standards
(c) applicable risk management outcomes;
(d) where appropriate, information derived from previous similar designs;
(e) other essential requirements for the development of the product and processes.
These submissions must be assessed for appropriateness and approved.
Requirements shall be complete, unambiguous, verifiable or prone to validation and shall not contradict each other.

7.3.4 Development results

Development results must be:
(a) meet the requirements for development inputs
(b) provide appropriate information for procurement and production;
(c) contain or refer to acceptance criteria for the product;
(d) define the characteristics of the product which are essential for safe use.
The design results shall be approved prior to release and records of the design results shall be maintained.

7.3.5 Development evaluation

In appropriate phases, systematic development evaluations must be carried out according to planned and documented regulations in order to
(a) assess the ability of the development results to meet the requirements
(b) identify and propose necessary measures.
Participants in such evaluations shall include representatives of the functional areas concerned with the development phase under evaluation and other experts, and records shall be maintained of the results of the evaluations and of any necessary actions taken, including identification of the design evaluated, the participants involved and the date of the evaluation.

7.3.6 Development verification

Development verification shall be performed according to planned and documented arrangements to ensure that the results meet the requirements for development inputs. Dr. Arabin GmbH & Co KG documents verification plans, which contain methods, acceptance criteria and statistical methods with justification for the sample size. If the intended use requires the medical device to be connected to or have an interface with another medical device, verification shall include confirmation that the design results after connection or use of an interface are in accordance with the design input. Records will be maintained of the results, conclusions of the verification and necessary actions. .

7.3.7 Development validation

A development validation is carried out according to planned and documented regulations to ensure that the resulting product meets the requirements for the specified application or intended use.
Dr. Arabin GmbH & Co KG documents validation plans that include methods, acceptance criteria and, if appropriate, statistical methods with justification for the sample size.
A development validation is performed on a representative product. that the first production unit may include the first batch or equivalent. The rationale for the selection of the product used for the validation shall be recorded (see 4.2.5).
As part of the development validation, Dr. Arabin GmbH & Co KG must perform clinical evaluations or performance assessments of the medical device in accordance with applicable regulatory requirements. A medical device that is used for clinical evaluation is not considered to be released for further use by the customer.
If the intended use requires the medical device to be connected to another medical device, the validation must include a confirmation that the requirements for the specified application or intended use have been met. Validation must be completed before the product is released for use by the customer. Records of the results and conclusions of the validation and necessary actions must be maintained (see 4.2.4 and 4.2.5).

7.3.8 Transfer of development

The Dr. Arabin GmbH & Co KG documents procedures for the transfer of development results. These procedures shall ensure that the development results are verified as suitable before they become final specifications for production and that the production capability can meet the product requirements.
The results and conclusions of the transfer must be recorded (see 4.2.5).

7.3.9 Managing development change

The Dr. Arabin GmbH & Co KG documents procedures to guide development changes and determines the significance of the change to function and safety under applicable regulatory requirements for the medical device and its use. Development changes must be identified. *Before* their implementation, the changes must be:
(a) examined;
(b) verified;
(c) validated, where appropriate;
(d) be approved.
The evaluation of development changes must include an assessment of the impact of the changes on components and products to be processed or already supplied, inputs or results from risk management and product realisation processes.
Records shall be maintained of changes, their evaluation and all necessary actions (see 4.2.5).

7.3.10 Development files

The Dr. Arabin GmbH & Co KG maintains a development file for each type of medical device or group of medical devices. This file contains records or references established to demonstrate conformity with the development requirements and records of development changes.

7.4 Procurement

7.4.1 Procurement processes

Dr. Arabin GmbH & Co KG has established a corresponding procedure to ensure our product quality. This enables us to assess whether all products/services meet the specified quality requirements and whether our (future) suppliers are capable of meeting our requirements. All suppliers are managed in the merchandise management system and undergo an annual supplier evaluation based on objective and subjective criteria. New suppliers must be qualified in the course of an initial assessment. In the event of deviations of a supplier (even during the course of the year), appropriate measures are to be taken, which can lead to the exclusion of the supplier.

Other applicable SOPs
SOP 07.4.1-01 Procurement and supplier management

7.4.2 Procurement information

The procurement data of Dr. Arabin GmbH & Co KG clearly contain the ordered product or service. Orders should be made in writing and will be reviewed for appropriateness before being submitted to the supplier or service provider.
The supplier must notify Dr. Arabin GmbH & Co KG of any changes to the procured product before implementing any changes. This applies in particular to changes that affect the suitability of the procured product to meet specified procurement requirements.

7.4.3 Goods receipt / verification of procurements

All procured products are tested at Dr. Arabin GmbH & Co KG. The nature and scope of such testing activities depend on the product to be procured and are determined individually on the basis of the risk involved. This ensures that the identity and quantity of the products received match the order placed.
In the context of special quality requirements of the products to be procured, further tests and the associated documentation may be necessary. Should Dr. Arabin GmbH & Co KG become aware of any changes to the procured product, it will be determined immediately whether these changes affect the product realization process or the respective medical device.

Other applicable SOPs
SOP 07.4.3-01 Incoming goods inspection
SOP 07.4-3-02 Test status

7.5 Production and service provision

7.5.1 Control of production and service provision

The production and service provision at Dr. Arabin GmbH & Co KG is controlled by established procedures in order to meet the product specifications laid down in the technical documentation.
The procedures also include specifications for product release and for activities after delivery. The documentation of the required and performed processes is carried out in general and in documents accompanying the production process at each manufacturer. In this way the manufacturing process or service activity can be controlled and the quality of the products can be ensured. The documented traceability of the products is ensured by batch numbers in accompanying documents.

Other applicable SOPs
SOP 07.5.1-01 Steering Product realisation
SOP 07.5.1-02 to -05 Production (SynerSilt-DINO-AG , Schneider-Büdenbender-Rusu , Van Kempen, WEZO)
SOP 07.5.1-06 Process control further processing
SOP 07.5.1.-07 Visual inspection Storage, packaging, dispatch

7.5.2 Cleanliness of products

The Dr. Arabin GmbH & Co KG has defined measures to control the germ contamination of the pessaries by external suppliers ("bioburden"). Appropriate quality assurance measures additionally ensure that there is no risk of infection for patients at any time.

7.5.3 Activities during installation

All pessary types from Dr. Arabin GmbH & Co KG do not require installation in the technical sense. The selection of the respective sizes is described in the corresponding instructions for use for the medical profession. ***Therefore, this standard element is considered not to be applicable***.

7.5.4 Maintenance activities

All pessary types from Dr. Arabin GmbH & Co KG do not require any maintenance in the technical sense. The cleaning that may be necessary during use is described in the respective instructions for use. ***Therefore, this standard element is considered not to be applicable.***

7.5.5 Special requirements for sterile medical devices

All pessary types from Dr. Arabin GmbH & Co KG are marketed non-sterile. It is not necessary to sterilise the products to ensure that they can be used according to their intended purpose. ***Therefore, this standard element is considered not to be applicable***.

7.5.6 Validation of processes for production and service provision

Currently, there are no processes at Dr. Arabin GmbH & Co KG that require validation in the context of production and service provision. Possible future processes of the production and service provision of Dr. Arabin GmbH & Co KG, whose results cannot be verified by monitoring or measurement, or where deficiencies only become apparent after the product has been put into use, are validated.
Validation plans are created to carry out the validation. Validation protocols and validation records are documented and the resulting results are evaluated and summarized in the corresponding validation report. It must demonstrate that the process is capable of delivering the expected results.
Computer software used in the production and provision of services is validated before first use and, if necessary, also revalidated after changes to this software or its application. Appropriate records are kept.

Other applicable SOP
SOP 07.5.6-01 Order processing

7.5.7 Special requirements for validation of sterilization processes/ sterile barrier systems

All products of Dr. Arabin GmbH & Co KG are marketed non-sterile. It is not necessary to sterilise the products to ensure that they can be used according to their intended purpose. ***Therefore, this standard element is considered not to be applicable.***

7.5.8 Identification

Identification of procured products and any intermediate products as well as the final products is possible via the respective article number or assigned production batch. The final products receive a product batch, which may consist of several production batches due to different components. The corresponding test status of the product can be identified at any time via the respective accompanying documents. Documented procedures are in place to uniquely identify returned products.

7.5.9 Traceability

7.5.9.1 General

For each medical device, records are kept in accordance with the applicable regulatory requirements, documenting the quantity produced, the components or parts for manufacture, the related equipment, the persons performing the work and the delivery information, so that traceability from production (including deliveries from raw material suppliers) to the customer can be traced via the merchandise management system.

7.5.9.2 Special requirements for implantable medical devices

All pessary variants of Dr. Arabin GmbH & Co KG are not implants. ***Therefore, this standard element is considered not to be applicable.***

Other applicable SOP
SOP 07.5.9-01 Identification and traceability

7.5.10 Property of the customer

Corresponding products are marked as customer property upon receipt by Dr. Arabin GmbH & Co KG. The further procedure must be discussed with the customer and documented in writing. Dr. Arabin GmbH & Co KG also understands customer property to include intellectual property, documents (including regulations/prescriptions), drawings or confidential information. Should customer property be made accessible to third parties, the customer must be informed immediately in order to discuss further proceedings.
In case of loss, damage or unusability of a product provided by the customer, this will be documented and the customer will be informed immediately.

7.5.11 Product preservation

The processes for manufacturing, further processing, storage, distribution and the corresponding technical documentation of the medical devices regulate the procedures and requirements for maintaining the conformity of the product components or intermediate products and the later final medical devices in the respective process steps.

7.6 Control of monitoring and measuring equipment

All measuring equipment (test equipment) at Dr. Arabin GmbH & Co KG, which is used to ensure valid test results of product conformity, is subject to control and can be clearly identified. In order to maintain our product quality, we ensure the calibration of these measuring instruments in accordance with the normative requirements and provide for proper handling and storage to avoid damage and deterioration of the measuring instruments used by us.
In case of a measuring equipment failure due to a detected damage or deviations outside the permissible tolerance range, measures are taken to evaluate previous test results. The use of measuring equipment and the corresponding test results are part of the product documentation.

Other applicable SOPs
SOP 07.6-01 Test equipment management

8. Measurement, analysis and improvement

8.1 General information

The Dr. Arabin GmbH & Co KG has defined and implemented the necessary monitoring, measuring, analysis and improvement processes to demonstrate the conformity of the products and to ensure and maintain the effectiveness of the QM system. The responsibility lies with the management in cooperation with the QMB.

8.2 Monitoring and measurement

8.2.1 Feedback signals

The Dr. Arabin GmbH & Co. has established a feedback system which contains provisions for the collection of data from production as well as for activities after production. The results are incorporated into risk management and the product realization or improvement process.

8.2.2 Complaint processing

Dr. Arabin GmbH & Co. has established a procedure for the timely processing of complaints in accordance with applicable regulatory requirements.

8.2.3 Reporting to regulatory authorities

Dr. Arabin GmbH & Co. has implemented a procedure for providing notifications to the relevant regulatory authorities. The notifications are made in accordance with the requirements of MEDDEV 2.12-1 "Guidelines on a medical devices vigilance system".

8.2.4 Internal audit

The QM system of the Dr. Arabin GmbH & Co. is checked annually by an internal audit in accordance with the specifications in the associated procedure. This is to determine whether the QM system effectively implements and maintains the planned and documented regulations, the requirements of EN ISO 13485, the requirements specified by the Dr. Arabin GmbH & Co. and the applicable regulatory requirements.
Measures are taken to eliminate recognized errors and their causes and their effectiveness is checked. The results of the internal audit are incorporated into the management assessment. The selection of auditors and the conduct of the audit ensure the objectivity and impartiality of the audit process.

Other applicable SOP
SOP 08.2.1-01 Feedback and complaints
SOP 08.2.4-01 Internal audit

8.2.5 Monitoring and measurement of processes

The Dr. Arabin GmbH & Co. applies suitable methods for monitoring and measuring the processes of the QM system. Wherever possible, these are determined directly within the procedure. If the planned results are not achieved, corrective and remedial action must be taken where appropriate.

8.2.6 Monitoring and measuring the product

The Dr. Arabin GmbH & Co. records all necessary characteristics of its products and systematically monitors the fulfilment of the requirements in suitable intermediate and final tests. Proof of conformity shall be documented in production records and batch records. The function and the name of the person performing the procedure are always evident from the records. The test equipment used is also noted.

8.3 Steering of non-conforming products.

8.3.1 General

The Dr. Arabin GmbH & Co. ensures that a product that does not meet the product requirements is marked and directed to prevent unintentional use or application on the patient (delivery). The control measures, responsibilities and authorities for dealing with non-compliant products are defined in the associated procedure.

8.3.2 Actions in response to non-compliant products detected before delivery

Non-conforming products that are identified before delivery must always be marked accordingly immediately. Further specifications, such as associated responsibilities and authorities for handling non-compliant products (or services) are described in the associated procedure.

8.3.3 Action in response to non-compliant products detected after delivery

If a non-conforming product is only detected after delivery or application has already begun, the safety officer of Dr. Arabin GmbH & Co. is responsible for further action. The activities to be carried out are defined in the associated procedural instructions.

8.3.4 Rework

Reworking in the sense of necessary corrections will only be carried out by Dr. Arabin GmbH & Co. in exceptional cases and only after approval by the management. The amount of rework is proportional to the risk. The associated procedure describes the procedure.

Other applicable SOP

SOP 08.3-01 Steering of non-conforming products
SOP 08.3-02 Handling of return deliveries and complaints
SOP 08.3-03 Rework

8.4 Data analysis

In order to be able to assess the suitability and effectiveness of the QM system, data from the following areas is determined, recorded, analysed and documented as part of the management review:

- Documents on the suitability, effectiveness and appropriateness of the QM system (quality objectives, management evaluation, development documents, risks, training)
- Feedback
- Declaration of conformity of the product with the product requirements
- Process and product characteristics including opportunities for improvement
- Supplier assessments and contracts
- Audits

Other applicable SOP

SOP 08.4-01 Data analysis
SOP 08.4-02 Post marketing Clinical Follow-up Plan
SOP 08.4-03 Post marketing surveillance plan

8.5 Improvement

8.5.1 General information

The Dr. Arabin GmbH & Co. determines and implements all changes that are necessary to ensure and maintain the continued suitability, appropriateness and effectiveness of the QM system as well as to ensure and perform the medical device. For this purpose:

- Forms on quality policy and quality objectives
- Results from audits and their follow-up,
- Surveillance analyses after "placing on the market" of products
- Data analyses
- Corrective and preventive measures
- Management Assessments

Analysis results serve as a basis for possible corrective and preventive measures.

8.5.2 Corrective actions &
8.5.3 Preventive measures (CAPA)

The Dr. Arabin GmbH & Co. has established a procedure for the handling and implementation of corrective and preventive actions with consecutive numbering and date.

Other applicable SOPs

SOP 08.5.2-01 Corrective and preventive actions