1. General

1.1 Purpose

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Minato Medical Science Co., Ltd. Nishiki Office, Kobe Office, Shizuoka Office and Headquarters (hereinafter referred to as "our office") have set forth this provision in our quality management system ( hereinafter referred to as "quality system") in documents and The purpose is to establish standards necessary for the handling of record creation, processing, storage, disposal, etc., and to manage documents and records appropriately.

1.2 Scope

This provision shall apply to the documents and records listed in the separately defined “Document Records List”.

1.3 \_　responsibility

Responsibility for the management of individual documents and records rests with the person in charge of the original document storage department for the separately defined "document record list".

2. Document management

2.1 Paper standards

As a general rule, the paper used for document creation, including those that are converted to electronic data, shall be A4 size, the Japanese standard size. However, if A4 size cannot be used for records, drawings, etc., other columns A or B may be used.

2.2 Management of creation, approval, distribution and collection

1. In order to clarify the management of documents, the creation department, approver, distribution destination, and original storage department are specified. determine. Details are based on the separately defined “Document Record List”. Documents should be written clearly, and the date of creation or revision, drafter (creator or revisioner), and approver should be specified so that they can be easily identified. The revision history of the instruction manual shall be separately recorded in the “Attachment Document Revision History Record”.

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(Note) If the person in charge of the engineering department or the person in charge of the production department is the approver, the approval can be delegated to a lower-ranking person in the organization concerned.

1. The quality system manager reviews, updates, and re-approves documents when:

・When related standards and regulations are changed.

・When the organization has changed significantly.

• When the applicable quality system standard is changed.

For re-approval, record the reason for the review in the revision reason column.

1. The person in charge of the department to which the document is distributed manages the replacement and disposal of the document. When the quality manual is revised, the technical and legal affairs section records the version number and revision date in the document distribution ledger.
2. Procedures for posting in an electronic file format on the company LAN
3. It is distributed by uploading it to the company LAN. Older editions are managed by the department that issued them (Quality Manuals and Operational Procedures are handled by the Technical and Legal Affairs Section).
4. Documents are basically browsed through the company LAN. However, it is possible to print and use it if it is necessary for business execution, such as a procedure manual related to manufacturing.
5. The person in charge of the department that receives external documents (laws, standards, other regulatory documents, delivery specifications, product catalogs) confirms the appropriateness of the content. The person in charge of the relevant department will clarify and manage the confirmed external documents.
6. In order to prevent misuse, the originals and copies of the documents to be abolished shall be managed by the person in charge of the original storage department, and by the person in charge of the department who received the copies. When obsolete documents are retained as reference documents, they are identified by displaying "obsolete".

2.3 Management of record forms

1. The person in charge of each department confirms the appropriateness of the newly created recording form, registers it in the "recording form ledger", and approves it on the "recording form ledger". However, for records that do not have a document code such as minutes in the separately defined "document record list" and record forms that do not require approval of the form itself such as appointment records, various lists, data analysis records, etc. registration to the .
2. The person in charge of each department clarifies the changed version of the recording format and the distribution destination in the “recording format ledger” and distributes a copy of the recording format to the distribution destination. The collection and disposal of old versions and their copies will be managed by the person in charge of the department that received them.

2.4 Non-controlled documents

the quality manual outside of our company or for educational and training purposes within our company , the person in charge of the original storage department will stamp the cover with a "non-management" stamp and distribute it, and the version will be managed. Make it not exist.

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2.5 Temporary drawing

1. As an interim measure pending the issuance of a revised version of the manufacturing documentation, a preliminary drawing may be issued and distributed to the manufacturing site.
2. Temporary drawings will be issued by the person in charge of the process control section. In addition, if the content of the provisional drawing includes technical elements, it shall be confirmed by the Research Division before issuance.
3. After the revised version of the manufacturing-related document is issued, the relevant temporary drawing shall be removed from the manufacturing site and kept by the person in charge of the process control section. The person in charge of the distributed department manages replacement and disposal.

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2.6 Document code

1. In principle, a document code (document number) is attached to the document.
2. Document codes shall be assigned in accordance with Table 1 of this provision. Document codes will not be attached to external documents and records that do not require a specific format.

2.7 Amendments

1. We will promptly revise each document if it becomes necessary to revise it.
2. Approval of revised documents and other management shall be based on the separately defined “document record list”. However, in the case of approval of revisions that are not essential changes in the document, but that have been partially expanded to make them easier to use, or that supplementary explanations have been added, even if the person who originally approved the revision does not It can be revised with the approval of the person in charge of the department to which the department belongs.
3. After revision, a copy will be distributed to the relevant departments promptly after approval. Distribution destinations are according to each management table / record format ledger.
4. The old document before replacement, which has become invalid due to revision, shall be promptly discarded under the responsibility of the person in charge of the department to which it was distributed. When these old documents before replacement are retained as reference documents, they are identified by displaying "obsolete".

2.8 Documentation maintenance

1. The regulations and standards of the quality system must be managed so that they can be viewed by employees at any time.
2. Discontinued quality system regulations/standards, product standards, and recording forms that do not have a document code such as minutes, appointment records, various lists, data analysis records, etc. In order to guarantee the specifications of the medical device, the originals of the record forms excluding those not specified shall be retained for at least 15 years after discontinuation (for documents related to Europe, at least 10 years from the last shipment). There must be. In this case, it should be identified by displaying "obsolete".

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1. If the distributed document becomes difficult to use due to damage, etc., please notify the person in charge of the original document storage department and receive it.
2. Documents for which the reasons for keeping them have disappeared can be discarded after consultation with the relevant departments and with the approval of the approver of the separately defined "document record list".

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2.9 Management of Product Standards

Regarding the composition documents of the product standards specified separately in the "document record list", under the direction and supervision of the person in charge of the technical legal affairs section, the person in charge of the technical legal affairs section creates a list of links to each electronic file storage location for each product Posted on company LAN.

3. Records management and storage

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* 1. our company , we will clarify the records to be created and maintained, the original storage department, and the storage period in the separately defined "document record list". Records shall be retained for at least the period specified in the separately defined “Document Record List” from the date of recording.
  2. Records shall be filed or converted to electronic data by type or genus, and in the case of filing, the name of the record and the original storage department shall be indicated on the back cover of the file. For records that have been converted to electronic data, the name of the record must be specified in the electronic data or in the folder in which it is stored.
  3. The documents shall be stored at the location designated by the person in charge of the original document storage department. Records converted to electronic data are stored on a designated server where backup and other management is properly performed.
  4. In March of each year, the person in charge of the original document storage department disposes of the documents that have passed the storage period and are judged to be discarded. Records that have been converted to electronic data are transferred to a dedicated folder for disposal.

Files that have been filed may be discarded in units of files, with the latest recording date in the file as the starting point of the storage period.

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* 1. If the record contains confidential customer health information, its handling is subject to our Privacy Policy.

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* 1. When amending records, do so in such a way that the original entries are identifiable, and keep a history of the changes.

4. Other Matters

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the approver of the recording department covers the Nishiki, Kobe and Shizuoka factories, the approval will be done by fax, e-mail, etc.

(Appendix 1)

1. Document format

Among the documents, quality manuals and regulations ( ZMG ) shall be in the following header format, and the revision history table shall be clearly marked with the version number, revision date, approver, etc. to identify the document. For other documents, no particular format is prescribed.

【品質マニュアル】



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改定日

新規制定時は１とし、以降は改訂毎に増加する

【規定】



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○○○○規定 ZMGnnnn Rev. n＃ 2018/5/21 Page 1 of 5

新規制定時は1とする。最初の改訂は1Aとし、文中の改訂箇所にAを表記する。以降は改訂毎にB、C、・・・とする。変更箇所が相当数になり判読しづらくなった場合は2Aとする。以下、同様に改訂時に改訂番号・記号を更新する。

2. How to add a document code

Quality Manual: ZMG1000

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ｇ・ｎは数字を意味し、

＃はアルファベットを意味する。

但し、ｇは次のグループ番号を

表す。

1：電気治療系

2：電波治療系

3：リハビリ系

4：整形治療系

5：測定器系

6：その他

7：共通

8：水治療系

9：肺機能系

Rules: ZMGnnnn (regulations related to business management)

ZBMnnnn (Regulations related to management of drawings)

ZQGnnnn ( Regulations related to compliance with QMS Ministerial Ordinance)

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ZVGnnnn (Regulations related to compliance with GVP Ministerial Ordinance)

ZMDnnnn (regulations related to compliance with MDD/MDR)

Criteria / Standards: ZMGnnnn (Criteria for Management / Performance of Work)

ZMGn#. Item name (Management criteria for each product)

ZPMn#nnn (manufacturing tools / manufacturing work management standards)

ZPSgnnn (standard for manufacturing operations)

ZSTgnnn (company standard table )

Instruction/procedure ZPMn#nnn (inspection procedure / work procedure)

/ Others: ZCDgnnn (circuit diagram)

ZTLgnnn (attachment)

ZTMgnnn (instruction manual : Japanese)

ZTNgnnn (instruction manual : foreign language)

C

ZTTnnnn (design change record)

ZSMgnnn (repair manual)

Parts code (Parts drawing according to company specifications)

Recording format (Note): ZMGn#nnn ( Mainly records related to business management regulations )

ZMGnnnn# (mainly a ledger/list derived from regulations related to business management)

ZPMn#nnn (mainly records related to manufacturing control / inspection)

ZTSnnnn 　 (Information related to product technology)

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ZSMn# Item (Installation check sheet)

ZSMn# g nnn (Repair check sheet)

ZQGn#nnn ( Mainly records related to regulations related to compliance with QMS Ministerial Ordinance )

ZMDn#nnn (Mainly records related to MDD/MDR compliance regulations)

(Note) When revising the record form, we will manage the version, and the first revision will be Ver.A1 .

After revising to Ver.A9 , numbering will start from Ver.B1 .

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| --- | --- | --- | --- | --- | --- |
| Revision History Table | | | | | |
| Edition number | Revision date | Revision items and reasons for revision | approval | confirmation | draft |
| 10A | 2018/05/21 | [document name]  Changed "Quality document and record management regulations " to "Document management regulations ".  [1.1 Purpose]  Deleted because it is defined in the quality manual, which is a higher-level document.  [2.5 Temporary drawing (3)]  aligned with reality.  [Table 1 ]  1. Changed the header style in the style of the document. | Kurisu | Yu Watanabe | Hikaru Ishii |
| 10B | 2018 / 12/2 7 | [3. Record management and storage]  Added items related to the handling of confidential health information as Section 3.5. | Kurisu | Yu Watanabe | Hikaru Ishii |
| 1 0C | 2 022/1/6 | [Table 1 ]  2. Added how to add a document code. | Arimoto | Mukaibayashi | Nomura |
| 1 0D | 2 022/2/10 | [2.2 Management of creation, approval, distribution, and collection ]  Regarding the revision history of the instruction manual, it was added that it should be separately recorded in the “Revision History Record for Attached Documents, etc.” | Arimoto | Watanabe | Nomura |
| 1 0E | 2 023/3/28 | [2.4 Uncontrolled Documents ]  [3.　Record Management and Storage 3.1]  [ 4. Other Matters]  Corrected the description deficiencies in the 10A revision.  [2.8 Document maintenance ]  Added retention period for European documents .  [2.9 Management of Product Standards ]  Stipulated the management method of product standards.  [3. Record Management and Storage 3.6]  Stipulated how to correct records. | Mukaibayashi | Ishii | Nomura |
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