1. General

1.1 Purpose

The purpose of this provision is to clarify the implementation procedures for corrective actions and preventive actions in our quality management system. 1.2 Liability

Responsibility for corrective and preventive actions rests with the quality system manager.

1.3

Definitions Complaint: Any complaint concerning the identity, quality, durability, reliability, usability, safety, or performance of a marketed medical device.

A. Any written, electronic, or verbal communication pointing out a service-related defect or service-related defect that affects performance.

2. Corrective

Action 2.1 Due to Customer Complaints Submitted to CS Conference

A. ~~Note) Complaints: to point out deficiencies in the identification, quality, durability, reliability, safety or performance of medical devices on the market, Any written, electronic, or verbal communication.~~

(1) Regarding complaints from customers, if the sales department (including the trade section), technical service staff, and TS staff obtain information from customers that may correspond to complaints, Enter the information in the “Repair CS Request Form (EDP)” or instruct the sales department (including the trade section)

A. or technical service staff that is the source of the information to enter the information in the “Repair CS Request Form (EDP)”. If an employee other than the TS section staff obtains information that may correspond to a complaint, the information shall be communicated to the TS section staff. and ~~fill in the request form and the TS Section accepts~~ it.

A. (2) In response to complaints from customers, the TS section manager identifies the information entered in the “Repair CS Request Form (EDP)” as corresponding to the complaint. If a decision is made, the department in charge will be assigned according to the table below, and it will be a matter for consideration at the CS meeting.

Classification of	Department in charge
Complaints Complaints related to product design	Research
Division Complaints related to process	Manufacturing Section, Process Control Section, Material Section, Shipping Section

(3) The person in charge of the department in charge shall investigate the cause of the complaint concerning non-conforming products. Requests for product improvement are not treated as corrective actions.

(4) The CS meeting evaluates the necessity of corrective action based on the cause of the nonconformity, and decides whether or not to implement corrective action. However, if it is determined that the contents involve the implementation of the “notification issuance rules” or “recovery processing rules”, the relevant rules will be implemented together with the processing from (5) onwards. If correction is deemed unnecessary, the reason will be clarified in “CS meeting unmeasured items - reason record”.

(5) The person in charge of the department in charge shall implement the following without delay.

- implement corrective action;

A. —

testify.

• Confirm the effect (appropriateness) of the implemented measures. (6) The

A. TS section will respond to the complaint, including whether or not corrective action has been taken, by submitting a “repair CS request form (EDP)” and “CS meeting agenda”. In addition, create a “Complaint Record” that records the following items.

(a) content of the complaint;

(a) Generic name or brand name and serial number of the product in question

(b) Date and location of complaint, and complainant (c)

Details of complaint

(d) Date of manufacture

(b) Investigation

results (a) Investigation results of the product

in question (b) Investigation results of

testing and inspection records (c)

Investigation results of manufacturing

records (c) Judgment

A. based on investigation results (a) Necessity of

improvement (b) (d) Status of improvement measures

(confirmation of effects

A. (applicability)) (a) Details of

measures (b) Confirmation of effects (applicability) (c) Conformity of measures to regulatory requirements performance or product safety and non-adverse effects

inspection

2.2 Occurrence of nonconformity other than 2.1 Corrective

action shall be taken according to the following

procedure. (1) Confirm the details of the nonconformity that

occurred. (*1) a) If an inspector or worker finds a non-conforming product during each inspection process (acceptance inspection, in-process inspection,

final inspection, or other processes), the following shall be followed.

A. • Inspectors or workers who discover nonconforming products should report to the process control section through the person in charge of

each department.• The Process Control Section, as the department in charge, investigates the cause of the nonconformity,

Record" or "Corrective Action Record".

b) The person in charge of the department that confirmed the content of the nonconformity

If it is determined that the implementation of the c) If the manufacturing section discovers a non-conformity and the responsibility

A. lies with the manufacturing section, the manufacturing section will take corrective action as the department in charge.

When issuing the installation implementation record, the record will be circulated to the process control section by e-

A. mail. d) If an audit by an external organization points out non-compliance, the Technical and Legal Affairs Section assigns a department in

A. charge. (2) The department in charge identifies (investigates) the cause of the

A. nonconformity. (*1) (3) The department in charge evaluates the necessity of measures to ensure the prevention of recurrence

A. of the nonconformity. (*2) (4) The department in charge plans and implements necessary measures. (Revise the document as

A. necessary.) (5) The department in charge shall verify that the action has no adverse effect on the ability to comply with regulatory requirements or the safety of

the product.

A. (6) The department in charge plans and implements confirmation of the effect (appropriateness) of the implemented measures. (*3)

(7) (Note) Carry out the above (1) to (6) without delay. A delay means a delay that is not commensurate with the risk of nonconformity and no extension of the

A. corrective action completion date that would be inappropriate in this light is acceptable. In addition, when rescheduling the postponement of the

corrective action completion date for nonconformities identified in external audits, it is necessary to obtain agreement from the auditor that the

delay is commensurate with the risk of the nonconformity.

A. (Note) In addition, the records of (2) to (6) above are entered in the "Corrective Action Record" by the person in charge of each activity department, and

the quality system manager approves it. When requesting corrective action from the supplier, the "Nonconforming Product Record" shall be used

as a record of corrective action implementation.

A. (8) Implement corrective actions in accordance with (1) to (7) for nonconformities pointed out in audits by external organizations

*1: If an "abnormality handling record" has been issued, refer to that record. *2: If the nonconformity

is caused by design, it may be included in improvement activities in design management. *3: In appropriate cases, confirmation

of the effect (appropriateness) of the measures after implementing them for a certain period of time.

3. Preventive

measures Preventive measures shall be

implemented according to the following procedure. (1) The person in charge of each department collects and analyzes the following information to identify.

(a) Corrective action implementation

status (b) Conformity to product

requirements (c) Process characteristics

and trends (d) Supplier

A. ~~evaluation (e) Records of CS card analysis~~

data (~~e)~~ (f) Customer feedback

(f) (g) ~~Info~~rmation obtained at the time of

repair ~~(g)~~ (h) Amendments to laws and standards

(2) The person in charge of the relevant department decides whether or not preventive measures for (1) are necessary, and if it is determined that preventive measures are necessary, he/she formulates a plan for them. The judgment (and planning) of the necessity of preventive measures for revisions of laws and standards shall be input to management review.

(3) Responsible personnel in relevant departments shall implement preventive actions and ensure that such actions meet regulatory requirements. Verify that there is no adverse effect on the safety and performance of (4) The person

A. in charge of the relevant department plans and implements confirmation of the effectiveness (appropriateness) of preventive m~~easur~~es. (*3)

(5) The records of (1) to (4) above are recorded in the “Preventive Action Record” by the person in charge of each activity, and the quality system manager approves it. admit.

4. Records

The records related to this provision are “Non-conforming product record”, “Abnormal handling record”, “CS meeting unmeasured matters - reason record”, “Repair CS

A. request form (EDP)”, “CS meeting minutes”. ”, “Complaint Processing Record”, “Corrective Action Record”, and “Preventive Action Record”, and shall be retained for at least the period specified in the “Document Management Regulations” from the date of recording.

Revision History Table					
Version	Revision date	Revision items and reasons for revision	Approval	Confirmation	Draft
9A	3/3/2023	[1.3 Definitions] The definition of “complaint” is consistent with ISO 13485 Clause 3.4. [2.1 Customer complaints submitted to CS meetings] Deleted the definition of “complaints” that overlaps with the description in Section 1.3. [2.1 Complaints from customers submitted to CS meetings (1) (2)] The descriptions have been revised to reflect the actual situation. In relation to the response to the findings No.2 in the ISO/MDD (MDR) periodic review conducted in January 2023, if information that may correspond to complaints was obtained by a person other than the TS section staff Add correspondence. [2.1 Customer complaints submitted to CS meetings (6)] ”, ”CS meeting minutes””. [2.1 Customer complaints submitted to the CS meeting (6) (c)] Related to response to issue No. 3 in the ISO/MDD (MDR) periodic review conducted in January 2023 added the determination of the necessity of reporting to the regulatory authority as an item to be recorded in the complaint record. [2.1 Customer complaints submitted to the CS meeting (6) (d)] Added details about the status of improvement actions for consistency with the Complaint Processing Record Form. [2.2 Occurrence of nonconformity other than 2.1 (1) to (5)] Clarified subject. [2.2 Occurrence of nonconformity other than 2.1 (1) (8)] Moved the response to nonconformity pointed out in the audit by an external organization from (8) to (1). [2.2 Occurrence of non-compliance other than 2.1 (6)] [3. Preventive measures (4)] Clearly state that confirmation of effects will be planned. [2.1 Customer complaints submitted to CS meetings (5)] [2.2 Occurrence of nonconformities other than 2.1 (5)] [3. Preventive measures (3)] Modified to "not given." [2.2 Occurrence of non-compliance other than 2.1 (7)] Changed (7) to (Note). Added a note about delays in response to Finding No. 1 in the ISO/MDD (MDR) periodic review conducted in January 2023. [3. Preventive measures (1)] In response to the revision of data analysis management regulations, CS cards were excluded from the scope of data analysis. delete.	Mukaibayashi	Furue Watanabe	Nomura