**Quality Agreement for Critical Supplier**

# Between

|  |  |
| --- | --- |
| Name of the Supplier |  |
| Address of the Supplier |  |
| Represented person  |  |

# and

|  |  |
| --- | --- |
| Name of the Manufacturer |  |
| Address of the Manufacturer |  |
| Represented person  |  |

# 1. Administrative Elements

## 1.1 Scope

This agreement defines the Quality Agreement between the parties identified above. It defines the commitment both parties make to ensure that their respective products and services satisfy the quality and regulatory requirements concerning medical device manufacturing.

## 1.2 Products and Services Covered by this Agreement

This agreement applies to the products and services listed in the table below.

|  |  |
| --- | --- |
| Product name  | [Product name] |
| Service | [Service name] |

## 1.3 Term of Agreement

This agreement shall become effective and binding upon the date of the final signature. This agreement shall be effective for all orders present and in the future that will be confirmed before the termination of this agreement. The agreement may be terminated by either party giving 6 months written notice to the other party.

Changes or additions to this agreement require a written form in order to be effective.

# 2 Compliance

## 2.1 Specifications

Manufacturer defines specifications for the product and service Supplier provides. This could be in one of the following forms: drawings, reference to commercial specifications, identified brand names, or applicable standards. The specifications may be paper documents, electronic documents, or other appropriate media. Supplier undertakes to deliver product and service in full conformance to the agreed specifications.

## 2.2 Specification Changes

Changes to specifications are made by mutual agreement between Supplier and Manufacturer. In addition to agreement to the change, Supplier and Manufacturer will determine the effective date of the change. When the specifications include references to brand names, Supplier and Manufacturer will mutually agree on the implementation of any changes made in the brand name product.

## 2.3 Changes in Processes

Supplier shall promptly notify Manufacturer of changes in the product and service so the Manufacturer may determine whether the changes may affect the quality of a finished device.

## 2.4 Activity by Regulators, Notified Bodies, or Certification Bodies

Supplier shall promptly notify Manufacturer of any inspection or audit findings that impact safety, effectiveness, conformity, or availability of product and service Supplier provides to Manufacturer.

Upon the Manufacturer’s request, Supplier shall disclose the results of any inspections or audits and the associated cause and corrective action.

## 2.5 Third-Party Quality Agreements

Supplier shall have a Quality Agreement with Third-Party Suppliers used for production, packaging, testing, processing, or release. Upon Manufacturer’s request, the Supplier will provide a copy of the Quality Agreement.

# 3. Non-Conformance, Corrective and preventive measures, and Complaints

## 3.1 Corrective Action

### 3.1.1 Supplier Initiated Corrective Action

The Supplier shall initiate corrective action for all detected nonconforming material or service regardless of disposition. Corrective action shall include the following steps:

1. Identifying cause of non-conformity

2. Deciding if it is necessary to initiate corrective action depending on complexity of non-conformity

3. Planning corrective action

4. Implementing corrective action

5. Reviewing whether the action taken resulted in the elimination of causes of non-conformity

6. Reviewing whether the action does not have an adverse effect

Supplier shall keep records of these activities and make them available to the Manufacturer upon request.

If Supplier does not have any kind of Quality Management System implemented, Manufacturer will provide certain records and educate Supplier how to use them.

### 3.1.2 Manufacturer Initiated Corrective Action

If Manufacturer identifies a nonconformity after receipt of the Supplier product and service, Manufacturer will initiate corrective action according to the Procedure for Corrective and Preventive Action and inform Supplier about it.

Supplier will be involved in investigating the cause and proposing the corrective action. Supplier shall report the results of the corrective action to the Manufacturer within [number of days] working days of initiation. When the Corrective Action is not completed within [number of days] working days, the Supplier shall provide a status report every [number of days] working days until the corrective action is completed, but not to exceed 6 months. Supplier shall keep records of these activities and make them available to the Manufacturer upon request.

## 3.2 Complaints

### 3.2.1 Supplier Received Complaints

If Supplier receives a complaint related to the product, or any similar product, Supplier shall promptly notify Manufacturer.

Manufacturer will decide whether it is necessary to start any action about it or not.

### 3.2.2 Manufacturer Received Complaints

If Manufacturer receives a complaint related to the product of the Supplier, the Manufacturer will enter the complaint in Appendix 1 Customer Feedback Report and review and evaluate the complaint to determine whether an investigation is necessary according to the Procedure for Customer Communication Feedback and Complaints.

If the Manufacturer requires the Supplier’s assistance in the investigation, Manufacturer will follow the defined procedure for non-conforming products.

# 4. Audits

## 4.1 Manufacturer Audits of Supplier Facilities

The Supplier shall allow the Manufacturer, or its authorized representative, to perform audits of the Supplier’s facilities, systems, documentation, and other requirements related to this agreement. Audits shall be conducted at mutually agreed dates and times.

When conducting audits at the Supplier’s location, the Manufacturer will issue an Audit Report within [number of days] working days of the audit’s conclusion.

The Supplier shall issue a plan to determine the correction, cause, and corrective action for each finding within [number of days] days of the Audit Report’s issue date.

## 4.2 Auditing Supplier by Manufacturer’s Notify body

The Supplier shall allow the Manufacturer’s Notify body to perform audits of the Supplier’s facilities, systems, documentation, and other requirements related to this agreement.

Audits can be conducted at mutually agreed dates and times, or unannounced.

|  |  |  |
| --- | --- | --- |
| MANUFACTURER |  | SUPPLIER |
| Date |  |  | Date |  |
|  |  |  |
|  |  |  |
| Responsible person  |  | Responsible person |
|  |  |  |
|  |  |  |
| Signature |  | Signature |