Quality Agreement for Critical Supplier

Between ("Supplier")

Name of the Supplier	
[illegible]	
[illegible]	

and ("Manufacturer")

Name of the Manufacturer	
[illegible]	
[illegible]	

1. Administrative Elements

1.1. Scope

This agreement defines the Quality Agreement between the parties identified above. [illegible]

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]
[illegible]	[illegible]

1.3. Terms of the 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. [illegible]

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

Commented [AES1]: This agreement is obligatory for all suppliers that provide critical components of a service. E.g., main raw material, sterilization, packaging.

[illegible]

Commented [AES2]: Include your supplier's information.

Commented [AES3]: Include your organization's information.

Commented [AES4]: Choose the one that applies, or both if [illegible]

Commented [AES5]: You can delete this row if there are no [illegible]

Commented [AES6]: You can delete this row if there are no [illegible]

Commented [AES7]: Adapt to the organization's practice.

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.

Commented [AES8]: Choose the one that applies, or both if

Commented [AES9]: Choose the one that applies, or both if

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 the Manufacturer of any changes in the product and service so the Manufacturer may determine whether the changes may affect the quality of a finished device.

Commented [AES10]: Choose the one that applies, or both if

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

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

Commented [AES11]: Choose the one that applies, or both if

Upon the Manufacturer's request, the 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. Nonconformance, Corrective and Preventive Measures, and Complaints

3.1. Corrective Actions

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 nonconformity
2. Deciding if it is necessary to initiate corrective action depending on complexity of nonconformity
3. Planning corrective action
4. [illegible]
5. [illegible]
6. [illegible]

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

[illegible]

3.1.2. Manufacturer-Initiated Corrective Action

If the Manufacturer identifies a nonconformity after receipt of the Supplier's product and service, the 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. [illegible]

Commented [AES12]: Choose the one that applies, or both if [illegible]

Commented [AES13]: You can find a template for this [illegible]

Commented [AES14]: Insert a number of days that is [illegible]

Commented [AES15]: Insert a number of days that is [illegible]

Commented [AES16]: Insert a number of days that is [illegible]

3.2. Complaints

3.2.1. Supplier-Received Complaints

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

[illegible]

3.2.2. Manufacturer Received Complaints

If the Manufacturer receives a complaint related to the product of the Supplier, the Manufacturer will enter the complaint in 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.

[illegible]

Commented [AES17]: You can find a template for this [illegible]

Commented [AES18]: You can find a template for this [illegible]

4. Audits

4.1. Manufacturer Audits of Supplier's 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.

[redacted] working days of the audit's conclusion.

[redacted] days of the Audit Report's issue date.

Commented [AES19]: Insert a number of days that is [redacted]

Commented [AES20]: Insert a number of days that is [redacted]

4.2. Auditing Supplier by Manufacturer's Notified Body

The Supplier shall allow the Manufacturer's Notified Body to perform audits of the Supplier's facilities, systems, documentation, and other requirements related to this agreement.

[redacted]

MANUFACTURER	SUPPLIER
Date	Date
[redacted]	[redacted]
Signature	Signature

Commented [AES21]: Enter here job title and name of the [redacted]

Commented [AES22]: Enter here job title and name of the [redacted]