

[organization name]

## Quality Agreement for Subcontractor

### Between ("Subcontractor")

Name of the Subcontractor	
Address of the Subcontractor	
Telephone number	

### and ("Manufacturer")

Name of the Manufacturer	
Address of the Manufacturer	
Telephone number	

## 1. Administrative Elements

### 1.1. Scope

This agreement defines the Quality Agreement between the parties identified above. It defines the processes and activities that the subcontractor performs and services under the quality and regulatory requirements covering medical device manufacturing.

### 1.2. Processes Covered by this Agreement

This agreement applies to the processes listed in the table below.

Process	Process ID

### 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. This agreement may be terminated by either party giving 30 days written notice to the other party.

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

**Commented [AES1]:** This agreement must be used when a subcontractor performs certain processes instead of the manufacturer. It can be the whole production, some part of the production process (sterilization, packaging, plasticization), or some special part of the final product.

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

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

**Commented [AES4]:** As processes, you can include production of a medical device, production of a special part of the medical device, sterilization, packaging, plasticization, etc.

**Commented [AES5]:** Adapt to the organization's practice.

## 2. Compliance for Subcontractors that are not Certified According to Harmonized ISO 13485

Commented [AES6]: Use this section if the subcontractor is not certified according to ISO 13485.

### 2.1. Processes

Subcontractor agrees to perform the processes stated in point 1.2 of this agreement in accordance with harmonized ISO 13485 [and other relevant standards].

Commented [AES7]: You can delete this part, or include other relevant standards, such as ISO 9001:2015.

*Subcontractor undertakes to ensure all the necessary documentation confirming the compliance process with necessary applicable technical standards. If Subcontractor does not have enough resources to do this, Manufacturer will help them.*

### 2.2. Changes in Processes

Subcontractor shall promptly notify Manufacturer of changes in the processes so the Manufacturer may determine whether the change may affect the quality of a finished medical device.

### 2.3. Activity by Regulators, Notified Bodies, or Certification Bodies

Subcontractor shall promptly notify the Manufacturer of any inspection or audit findings that impact the safety, effectiveness, or conformity of processes Subcontractor provides to Manufacturer.

*Upon the Manufacturer's request, the Subcontractor shall discuss the results of any inspections or audits and the associated issues and corrective actions.*

### 2.4. Third-Party Quality Agreements

Subcontractor shall have a Quality Agreement with Third-Party Subcontractors used for production, packaging, testing, processing, or release.

*Upon Manufacturer's request, the Subcontractor will provide a copy of the Quality Agreement.*

## 3. Compliance for Subcontractors that are Certified According to Harmonized ISO 13485

Commented [AES8]: Use this section if the Subcontractor is certified according to ISO 13485.

### 3.1. Processes

Subcontractor agrees to perform the processes stated in point 1.2 of this agreement in accordance with harmonized ISO 13485 [and other relevant standards].

Commented [AES9]: You can delete this part or include other relevant standards, such as ISO 9001:2015.

The Subcontractor undertakes to effectively maintain its Quality Management System in accordance with ISO 13485, to regularly conduct audits with a recognized Certification Body, and to notify the Manufacturer of major and minor nonconformities raised during these audits.

*Subcontractor agrees to regularly monitor all regulatory and standard requirements (including ISO 13485, ISO 14971, ISO 134852, etc.) and to inform Manufacturer promptly of any change that may affect the Manufacturer's medical device.*

Commented [AES10]: Delete if any of the regulations do not apply to your device.

[organization name]

The Subcontractor agrees to notify the Manufacturer immediately in the event of a suspension of the ISO 9001 certificate.

### 3.2. Changes in Processes

Subcontractor shall promptly notify Manufacturer of any changes in the processes stated in point 1.2 of this agreement, or the Manufacturer may determine whether the changes may affect the quality of a finished item.

### 3.3. Activity by Regulators, Notified Bodies, or Certification Bodies

Subcontractor shall promptly notify the Manufacturer of any inspection that impacts the safety, effectiveness, conformity, or availability of processes Subcontractor provides to Manufacturer.

Upon the Manufacturer's request, Subcontractor shall discuss the results of any inspections or audits and the associated issues and corrective actions.

### 3.4. Third-Party Quality Agreements

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

## 4. Nonconformance, Corrective and Preventive Measures, and Complaints

### 4.1. Corrective Actions

#### 4.1.1. Subcontractor-Initiated Corrective Action

Subcontractor shall initiate corrective action for all detected nonconformities regardless of disposition. Corrective action shall be processed according to Subcontractor's corrective action procedure.

Subcontractor shall keep records of corrective actions and document nonconformities and make them available to the Manufacturer upon request.

#### 4.1.2. Manufacturer-Initiated Corrective Action

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

Subcontractor will be involved in investigating the cause and proposing the corrective action. Subcontractor shall report the results of the corrective action to the Manufacturer within [number of days] working days of initiation.

Upon the corrective action is not completed within [number of days] working days, the Subcontractor shall provide a status report every [number of days] working days until the corrective action is completed, but not to exceed 30 days. Subcontractor shall keep records of these reports and make them available to the Manufacturer upon request.

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

**Commented [AES12]:** You can find a template for this procedure in the Appendix 7.

**Commented [AES13]:** Insert a number of days that is appropriate for the complexity of the corrective action.

**Commented [AES14]:** Insert a number of days that is appropriate for the complexity of the corrective action.

**Commented [AES15]:** Insert a number of days that is appropriate for the complexity of the corrective action.

## 4.2. Complaints

### 4.2.1. Subcontractor-Received Complaints

If the Subcontractor receives a complaint related to the process, or a product/service, Subcontractor shall promptly notify the Manufacturer.

Manufacturer will decide whether it is necessary to start any action about this risk.

### 4.2.2. Manufacturer-Received Complaints

If the Manufacturer receives a complaint related to the process of the Subcontractor, 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**.

If the Manufacturer requires the Subcontractor's assistance in the investigation, Manufacturer will follow the defined procedure for manufacturing products.

Commented [AES16]: You can find a template for this

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

## 5. Audits

### 5.1. Manufacturer Audits of Subcontractor's Facilities

The Subcontractor shall allow the Manufacturer, or its authorized representative, to perform audits of the Subcontractor'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 Subcontractor's location, the Manufacturer will issue an Audit Report within [AES18] working days of the audit's completion.

The Subcontractor shall issue a letter to describe the corrective action and completion within the next working [AES19] days of the Audit Report's issue date.

Commented [AES18]: Insert a number of days that is

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

### 5.2. Auditing Subcontractor by Manufacturer's Notified Body

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

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

[organization name]

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[organization name]
Date _____
_____ _____ _____
Signature

[organization name]
Date _____
_____ _____ _____
Signature

Commented [AES20]: Enter the name and the job title of the \_\_\_\_\_

Commented [AES21]: Enter the name and the job title of the \_\_\_\_\_