



Comef
Italian Style & Quality for Medical Devices

QUALITY AGREEMENT

QUALITY AGREEMENT

between

_____ - **COMEF**
(Customer)

Rev. N. ____

CUSTOMER

<i>Name</i>	<i>Address:</i>
	<i>Key person:</i>

SUPPLIER

COMEF Srl	Address: VIA PAPA GIOVANNI XXIII, 174
	41012 CARPI (MO) – ITALY
	Key person: Duero Maria Rossi

This agreement shall become effective after the signature of the persons involved and will be valid for all the products manufactured by COMEF srl (the Supplier) for _____ *(Customer)*

No amendment, change, modifications or alteration of the terms and conditions of this agreement shall be binding upon either party unless in writing and signed by both sides.



1. Product specifications

For each products they are available the following documents:

- **DRAWING** (with the indication of the quotes and of the used raw materials);
- **PRODUCT SPECIFICATION** (where the types of control, sterilization packaging specifications are indicated);
- **MATERIAL SPECIFICATION** (where all the information about the raw material are reported).

This documentation will be provided on receipt of this agreement signed from you by approval and it will be kept updated by Comef, informing the customer every time there is a change.

CERTIFICATE OF COMPLIANCE

The “Material conformity declaration” is reported on the packing list and it is sent to the customer with each delivery.

2. Invariability clause

Any change that could affect the product (i.e. functionality, essential requirements and product’s characteristic) will be communicated to the customer in written form before its introduction.

3. Quality System requirement

Comef confirms that it is and it will be maintained a Quality System certified. The certificate released by the Notified Body will be sent to the customer after every change.

4. Responsibilities/Qualified persons

For the Customer:

Job title:	Name:
Plant Manager	
QA Manager	
CQ Manager	
Procurement Manager	
General Manager	

For Comef

Job title:	Name:
Plant Manager	Marco Stoppa
QA Manager	Cristina Maini
CQ Manager	Calin Nicolescu
Customer Service Manager	Lara Malossi
General Manager	Duero Maria Rossi

5. Process flow

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a) Purchasing and check of the raw materials and components

Comef has the responsibility to purchase and check the raw materials and the components.

b) Work environment

Comef manufactures in a controlled clean room area (class 8 according to ISO 14644-1).

c) Production and Control Process

Comef production is executed following its internal procedures that define also the type of the control (sampling plan, AQL, and the list of the non-conformities).

Qualified operators grant the control of the production.

d) Packaging and labelling

The packaging and labelling is executed following the specifications of Comef.

The products have to be packed, in the quantity established in the specification, in two PE bags and inserted inside a carton box.

Each box has to be identified with a label showing the following information:

- Comef product code;
- Customer product code;
- Product batch number;
- Quantity;
- Customer name.

The weight of the box has not to be over 25kg.

Boxes are located on Euro pallets ISPM 15 standard and completely wrapped by a protective film, in order to grant their good storage during the transport.

6. Lot/batch number and Traceability

All parts must have full traceability.

The key number has to be present in all the documents that follow the product during the production process.

Also the material and product codes will be mentioned on all related documents, ensuring that the goods are identical to the goods described in the agreed specifications.

7. Controls and Release

The sampling plans and the types of controls performed on the products are reported on the product specifications.

The product can be released by Comef only after the conformity of all controls and internal inspections performed during the manufacturing process, that shall be adequately indicated, and only after written confirmation of the QC Manager.

Comef will report in each packing list the “Material conformity declaration”.

8. Treatment of non-conformities (complaints)



The customer shall inform the Quality Manager of Comef immediately (by e-mail or by fax), in case a non conformity should be found providing the following information:

- Complainant plant/department;
- Person reporting the non-conformities;
- Date of complaint;
- Reference number;
- Product description: name, code, lot number,
- Date of occurrence;
- Details about the non conformities (detailed description of the detected defect, indication to know if the defect has been found during the incoming inspection or during the in-process control, number of units inspected and number of the units received, number of defective units found, and type of AQL applicated)
- Availability of samples.

This information shall be written in English or in Italian.

Comef grants that all the conformities complained will be deeply analysed and the necessary corrective actions will be taken. At the end of the investigation a communication of corrective actions will be sent to the complainant and the QA Manager will sign such a document.

Every activities of selection effected by the customer on the defective products have to be previously approved by Comef QA Manager and Customer Service Manager.

In case the selection is not possible, Comef will authorise to return back the material and will send ASAP a replacement.

9. Communication

Comef plant is available to receive a Quality Auditing from the identified representative of the customer plant and when necessary to launch the appropriate Corrective Actions.

10. Responsibility

Comef it is not responsible for any damage, loss or delays suffered by the customer for the forwarder negligence.

11. Applicable Law

The Italian law regulates the present agreement. The parties agree that for any eventual controversy related to the present agreement the court of competent jurisdiction is Modena

APPROVED BY:

Place _____

Place _____

Date _____

Date _____

For The Customer _____

for Comef _____

(Name - Job title) _____

(Name - Job title) D.M.Rossi – General Manager