QUALITY SPECIFICATION FOR SUPPLIES OF GOODS
Di GILARDONI S.p.A. a Socio Unico

SUMMARY

PREMISE

This specification defines the principles regulating the relationships between Gilardoni S.p.A. (hereinafter GILARDONI) and their suppliers as to the required Quality and Reliability for outsourced products and services and it represents an integral part of General Purchasing Conditions attached to the orders.

It also defines the procedure to obtain supply approval and the Arrivals Acceptance Control procedure adopted by GILARDONI.

1. SCOPE

The objective of this document is to assure that purchased products meet the requirements without exception in order to:

- Pursue the company policy "0 defects";
- Improve the quality of our products by reducing reworks and low added value activities;
- Have customer/supplier relationships defined so as to avoid quality problems of finished products.

2. GENERALITIES

Product quality and reliability are the result of the coordinated action of all the bodies that constitute a company.

The main activities that contribute to their achievement are:

- The project;
- The definition of processing and acceptance cycles;
- The choice of the piece of equipment (processing equipment and control instruments);
- Personnel training;
- Supplier control;
- Collection and distribution of information;
- Any corrective actions.

3. SUPPLIER REQUIREMENTS AND RESPONSIBILITIES

3.1. Quality assurance system

The supplier is responsible for the supplied product quality and for product risks (see EEC Directive n. 85/374 and its DPR 224/88, the latter is abrogated and merged into D. Lgs. 206/2005 and subsequent amendments).

The supplier must have an active and effective Quality Management system, preferably the certification according to at least the standard ISO 9001 in the latest version in force.

Additional quality Management System certifications may be considered as an added value.

The Supplier must have a control system that allows to assure supplied product conformity to all the quality provisions required or agreed with GILARDONI.

3.2. Technical documentation and information flow

The Supplier must have the technical documentation sent by the GILARDONI Purchasing Department, timely providing for the updates that reach them; if they are lacking of certain documents, they will have to ask for a copy to the Purchasing Department.

The Supplier will have to proceed, if necessary, with the update of their quality assurance system, based on GILARDONI documentation (drawings, regulations, specifications, tables, etc.)

The GILARDONI Technical Bodies are constantly available to provide further information or clarifications as to drawings, regulations, specifications, tests and control means.

If the technical documentation isn't exhaustive, GILARDONI will provide the supplier with a separate document *GQ164 – Specific Supply Requirements* through which all the specifications necessary for product realization, delivery/storage are communicated.

These requirements may relate to:

- Product requirements (including any environmental obligations);
- Process requirements (including any environmental requirements);
- Equipment requirements;
- Quality requirements;
- Sub-supplier requirements;
- Traceability requirements;
- Labelling, Storage, Logistics and Handling requirements.

3.3. Means of production, control and test of the supplier

The Supplier must have means of production, control and test in such quantities and conditions as to ensure product quality and reliability requirements.

If the supplier has no suitable means to carry out directly and autonomously certain controls and tests required by GILARDONI documentation, they must turn to external certified Laboratories and notify the Purchasing Department about the characteristics that they aren't able to verify.

3.4. Certificate of Quality and Conformity and/or Self-certification

If the Supplier produces components according to GILARDONI specifications or drawing, they must attach to the first serial production representative sampling the relevant Certificate of Quality and Conformity (*GQ163 – Supply Conformity Certificate*) through which they highlight the performed controls and the measured characteristics and require the authorization to serial production. In addition, in the following cases, the certificate, the delivery documents and each container must bear the additional indication required.

Cases to be reported with additional indication	**Indication to be displayed**
Samples for approval	SAMPLING
Changed lot of products *	CHANGE
Lot of variances	CONCESSION N. ….
** only for the first lot*	

If the Supplier produces or markets standardized or catalogue products, they must deliver a conformity certificate for the supplied product as an annex to the first sampling.

N.B. The supplies that will arrive without the Certificate of Quality and Conformity will be considered as lacking by GILARDONI Quality and they will be reported as nonconforming on the Supplies Quality diagram and they will be able to be returned as rejection.

3.5. Product marking

The Supplier must comply with any product marking requirements indicated in GILARDONI technical documentation and/or in the purchase order.

3.6. Changes

The Supplier must not accept and/or make changes unless GILARDONI Quality Department authorizes it.

The Supplier must not introduce any changes into production (of materials, dimensions, processing, treatments, etc.) without first having submitted the relevant sampling and having received an official approval of GILARDONI issued by Quality Department, which authorizes the change.

Once the Supplier has received the approval, they must report the first changed lot as required by clause 3.4.

3.7. Supply quality and conformity

Each product lot must be subjected to Supplier quality verification, except for the case in which a 100% acceptance is required, the Supplier can choose the type of sampling to be adopted, as long as this ensures the prescribed and/or agreed requirements.

It is understood that the whole lot can be rejected if at our Company we find:

- -even a single "not acceptable" element (rejection)
- -lack or incompleteness of the required certification (when it is defined in the purchase contract).

The observation of one of these conditions will always and however generate the issuance of a nonconformity report by GILARDONI Quality with report to the Supplier.

In addition, when a lot is deemed to be rejected in accordance with the above modalities, if the product is totally or partially recoverable by recovery and/or selection operations and this is necessary for contingent production needs, the Supplier will be requested to provide for this within the period indicated on the Nonconformity Report.

3.8. Concession request

If the Supplier encounters a nonconformity (non-compliance with the requirements of GILARDONI documentation), prior to proceeding to materials delivery, they will have to notify immediately and ask for supply authorization to GILARDONI Quality Department.

The request will have to be formalized on the *GQ162 – Concession Sheet* form and will have to be restricted to a limited quantity of pieces or to a limited time period. The concession request is therefore to be considered an exceptional case and the acceptance is bound to the detailed explanation of the corrective action that the supplier decided to implement to avoid the recurrence of the inconvenience that led to the request.

The request will have to be accompanied by 5 samples (or a different number to be agreed with GILARDONI Quality Department) for any tests that GILARDONI will intend to perform prior to the issuance of the response.

The response will be sent by GILARDONI in writing using the same *GQ162 – Concession Sheet* form, filling in the part of their competence, both in case of approval and refusal.

The lots that are supplied under concession will have to be clearly identified on each container with the indication "Supply under concession" and on the notes of the *GQ163 – Supply Conformity Certificate* by attaching a copy of the GILARDONI approval document.

If no concession is requested, the material that reaches GILARDONI will be treated as nonconforming.

3.9. Corrective actions

If the Supplier receives, through Quality Department, the report of a non-acceptable or nonconforming product, they will have to immediately adopt all the necessary measures to eliminate the causes that caused the defect, providing a written notice which specifies the causes, the corrective actions taken and their date of implementation.

Particularly, a first containment action will have to be defined to ensure GILARDONI that the deliveries following the report of nonconformity are exempt from the reported anomaly, even if they are already in transit.

Such action to protect GILARDONI must be maintained until the effectiveness of the final corrective action is verified.

The final and permanent corrective action must be extended to all the processes/products that pose the same occurred risk.

The recurrence of a nonconformity is an aggravating fact which is considered in the periodic supplier evaluation.

4. GILARDONI COMPETENCIES

4.1. Preventive supplier evaluation for qualification

Each Supplier selected by Purchasing Department must be qualified according to the *PR010 – Material Supply and Preservation* procedure with a specific suitability evaluation survey.

For this purpose, GILARDONI will visit the Supplier establishment and will issue an Evaluation Report indicating the Supplier suitability level (according to *PR010 – Material Supply and Preservation* procedure).

4.2. Supplier evaluation during supplying

Each Supplier that GILARDONI has qualified and authorized to supply will be followed throughout the course of the supplying to continuously evaluate their performance and reliability.

4.3. Supply quality report

GILARDONI will report to the Supplier any anomalies found through the following documents, based on the results of the acceptance performed at their establishment on the received product:

- Nonconformity Report
- Specific notification related to supply quality

The content of the above documents will be notified to the Supplier, both by email and by phone, to allow a timelier reaction.

4.4. GILARDONI measures following an insufficient qualitative trend

If the qualitative trend of the received product shows an "Insufficient qualitative service" and/or a downgrade in the supplier reliability level, GILARDONI reserves the right to take the measures deemed to be appropriate (reprimand letters, supplier convocation, qualitative technical verification at their site, reduction or cancellation of orders in progress, etc.).

4.5. Supplier convocation and qualitative technical verifications

As a result of what expressed in section 4.4, the Purchasing Department in agreement with the Quality Department can convene the supplier reporting the arguments to be examined, and at the conclusion of the meeting they will draft minutes related to the agreed measures, of which they will give a copy to the Supplier and to the Supplier Quality that will verify its implementation.

If abnormal situations are particularly serious or recurring, the Quality Department may decide to carry out verifications or inspections at the Supplier, to evaluate the causes of the qualitative worsening.

Such verifications, previously agreed between GILARDONI Quality Department and the Supplier, will be conducted by Supplier Quality. During verifications, the Supplier will have to make available their own control and test equipment, along with its personnel.

At the end of the verification the inspector will draft minutes of results that will be sent to the GILARDONI Purchasing Department to take the most appropriate measures.

The supplier allows the manufacturer, the manufacturer certification body and the competent authorities to implement inspective verifications, even without prior notice, at their own facility to meet requirements of binding nature, if necessary.

GILARDONI commits to carry out the market supervision activity, by timely notifying the supplier of any defectiveness or hidden faults on the assembled products in order to jointly identify and resolve the detected problems, in particular for the cases in which there is evidence of conditions implying the need to issue advisory notices.

5. SUPPLYING MODES AND REQUIREMENTS

5.1. Start of the supplying

The Supply of a newly designed or of first supply product and/or of a changed product must always be authorized by GILARDONI Quality Department through a Supply Approval, issued following a product sampling submitted by the Supplier.

With the approval, after controls and/or tests, GILARDONI establishes the suitability for the use of a specific product and consequently authorizes the supplier to produce.

If a Supplier produces before obtaining the Approval, they do so at their own risk.

The Supplier of standardized and catalogued material is authorized to deliver the material without an official approval following the first certified delivery.

5.2. Supplies subject to sampling

- Newly designed product;
- Product already in use built with new equipment;
- Product already in use built by a new supplier;
- product already in use, manufactured by a supplier included in the approved list after a 3-year supply chain downtime;
- Product already in use on which changes have been made;
- Product already in use built with equipment subject to extraordinary maintenance;
- Product already in use built with a different production cycle and/or different material.

NOTE, the construction of a device, component, product made following a change in production lay-out, a relocation of production equipment/facilities within the same building or following the transfer to a new building, requires a written notification of the change by the Supplier to GILARDONI Quality Department, who will reserve the right to request sampling if the risk assessment makes it necessary.

5.3. Sampling mode

To obtain the approval of a product, the Supplier must submit a product sampling, following a regular "order" or "request" issued by GILARDONI Purchasing Department.

The sampling must reach GILARDONI Quality Department with the indication "SAMPLING" (see par. 3.4) and with a regular *GQ163 – Supply Conformity Certificate* or equivalent form indicating:

- The reason for sampling;
- The Supplier acceptance report indicating the controls carried out and the relative results.

In addition, the final Control Plan must be attached, unless otherwise agreed with GILARDONI DQ. The Control Plan must be made available to GILARDONI during the offer/order stage.

If a product is built with a multi-shaped mould, each shape must be clearly identifiable by a number, letter or other sign suitable for the purpose.

5.4. Sampling size

Unless otherwise agreed, sampling must be received in the following quantities:

- if the product is constructed with a multi-figure mould, (identical figures) --> 5 elements;
- if the product is built on a mould with several figures (different figures) --> 5 elements per figure;
- in other cases --> 5 elements.

If appropriate, Quality Department can require an additional and more considerable sampling for application, assembly, laboratory, finished product tests etc…

5.5. Sampling acceptance report and supply Approval

The result of the acceptance of each sampling, positive or negative, will have to be notified to Purchasing Department, Technical Department, Production Department and to the Supplier, through an Approval Report in which all the necessary and binding indications are reported.

5.6. Documentation

The supply is regulated by the purchase order and the technical documentation (drawings, specifications, regulations, tables and various requirements) that GILARDONI Purchasing Department will send to the Supplier prior to the beginning of the supply itself.

During the supply, any changes to what is prescribed by the written documentation will reach the Supplier by written communication, through the Purchasing Department themselves.

5.7. Deposited reference sample

In case of particular criticality of the product to be supplied, and in all the cases in which GILARDONI deems it necessary, a reference sample will be made, consisting of two twin samples covered with lead, of which one will be deposited at the supplier through the Purchasing Department and the other at GILARDONI Quality Control.

Such sample will be used both for the conformity comparison in acceptance tests and as reference in case of objections.

5.8. Transport, packaging and identification

The product must be supplied into containers or packaging suitable for preserving the product from damages during the transport and the storage, including ESD protection packaging (where applicable).

They must provide enough safety guarantees during the period of transport, handling and storage.

The supplier assures the correct material storage, in an environment with normal cleanliness conditions, according to the modes suitable to ensure its preservation without deterioration or damage, by observing the following provisions:

Each package must bear the Material Identification Card with the following information:

- GILARDONI code
- Product name
- Quantity of the container
- Total quantity of the lot
- Number of packages
- Number and date of the Transport Document

Each package must contain only one GILARDONI code. If this is not possible, the contents of the package will have to be highlighted by a label to be affixed to the package, indicating the GILARDONI codes contained and the quantities.

The pallets must be packaged by code. If this is not possible, separate the codes with a cardboard separator. In case of pallets packaged with only one code, the maximum height must not exceed 1200mm.

5.9. Accurate identification of serial number/serial number

Where required and specified in the technical drawing, GILARDONI requires to identify the individual product with a label bearing at least the following information:

a. GILARDONI Code (UGIL)
b. GILARDONI Supplier identification code
c. Serial number

d. Month and year of production

Regarding the serial number, the same must be built using 9 digits, of which, the first 6 deriving from our supply order and the remaining 3, progressive starting from 001, as many as are the products delivered with the same batch.

UGIL 20012525
Cod. Forn. 102365
SN 025896001
09/22

Upon confirmation by GILARDONI, this information can be indicated on the label by using barcode, qrcode or datamatrix. The construction is the same as above using only the codes without the indications

e.g. 20012525-102365-025896001-09/22)

Regarding the size of any labels will be, or defined within the design sent or will be defined by the supplier according to its standards or according to the size of the detail.

6. MODES OF OPERATION OF GILARDONI ARRIVALS ACCEPTANCE TEST

6.1. Purchase material control

All the products of external supply are subject to incoming control that verifies their relative qualitative characteristics, filtering the unacceptable lots.

6.2. Specifications for control

- Drawings and regulations

  For the acceptance of dimensions, processing and any other qualitative characteristics of external supply products, refer to drawings and regulations issued or recognized by GILARDONI and distributed to suppliers by Purchasing Department.

- Control cycle

  For each element of external supply, Quality Department drafts a Control Cycle, indicating the characteristics to be accepted with the relative frequency, sampling, means of acceptance, references to specific regulations and specifications and any other additional information necessary to define completely and to make the acceptance rational.

Additionally, Quality Department handles the updating of Control Cycles, by making all the useful variants to comply with the Customer's specifications, production needs, etc., indicating the updating date.

If there are no Control Cycles on the Computer System, refer to the general Control Instructions or to Product Control Sheets of the family to which the element belongs.

6.3. Statistical acceptance of Supply quality

Unless otherwise specified, GILARDONI Quality tests the lots of normal external supply according to the statistical acceptance by variables proposed by the software that handles the control cycles.

6.4. Nonconformity Report

As a result of any defectiveness detection, a Nonconformity will be issued for the relative objection, indicating in detail the defects found and the data useful to the Supplier to identify the lot.

The Nonconformity Report is sent to the Supplier by email and, when necessary, its content will be anticipated by phone to allow a faster corrective action.

7. INSTRUMENTS AND EQUIPMENT

7.1. Control of instruments / equipment effectiveness

The process/product verifications and acceptances defined by the supplier during their own productive cycle are performed with conveniently calibrated instrument and/or verified with calibrated samples.

7.2. Nonconformities management during equipment control calibration stage

If, during the periodic instrument calibration stage, an anomalous or out of control instrument is identified, the supplier must perform a risk analysis and inform GILARDONI if there is the risk that materials wrongly declared to be conform have been sent to the customer, so that any risk/impact towards the served market is determined.

8. SPECIFIC REQUIREMENTS FOR SUPPLIES INTENDED FOR THE MEDICAL MARKET

8.1. Measurement instruments traceability

The measurement instruments/equipment used to perform acceptances, functional and/or deliberation controls must be recorded on documents of process control record by the producer to allow the proper traceability on the lot or product.

8.2. Identification of risks derived by components purchased by the supplier

If the supplier, during the normal component purchasing relationship suitable for the manufacture of products for GILARDONI, is informed of the potential nonconformity or defectiveness of a supply by their own sub-supplier, they must notify the customer in a timely manner, in order to allow a proper risk evaluation.

Supplier signature and stamp for acceptance

Place _____

Date _____