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QUALITY AGREEMENT – FONDERIA TARONI

IDENTIFICATION OF PARTIES:

This agreement applies to

FONDERIA TARONI DI TARONI ROBERTO &C. snc

in the following referred to as **FONDERIA TARONI**

&

SUPPLIER NAME

in the following referred to as **SUPPLIER**

The SUPPLIER and FONDERIA TARONI shall observe the conditions set out herein and exchange information in the event of anomalous and/or unforeseen events. The SUPPLIER and FONDERIA TARONI undertake not to make any formal or substantial modifications to this Quality Agreement without prior mutual agreement.

PURPOSE

This procedure aims to successful manufacture of components and subassemblies provided by SUPPLIER and purchased by FONDERIA TARONI. The responsibility matrix below defines and deals with the necessary documentation and responsibilities.

The Quality Agreement is supplemented by a Supply Specification detailing all the technical information related to the products.

PERIOD OF AGREEMENT VALIDITY

This agreement shall come into force in the effective date and shall remain in effect until the end of the commercial agreements between parties.

DEFINITIONS:

PRODUCT: The devices and components supplied from SUPPLIER to FONDERIA TARONI. The product involved in this quality agreement are manufactured by the SUPPLIER under specification shared by FONDERIA TARONI.

SEMIFINISHED: Any device and / or component that has undergone a partial machining or processing which is provided by the SUPPLIER to FONDERIA TARONI.

DEVICE HISTORY RECORD: The actual production records for a particular device that shows the processes, tests, and rework used to produce a device. Includes component(s) used, manufacturing (assembly and packaging) procedures, inspection and test results, device labelling, and any other documentation required to produce the components and/or subassemblies.

DEVICE MASTER RECORD: The master listing of all procedures, specifications, and bills of material, which are required to produce a product.

DESIGN VALIDATION: Establishing by objective evidence that device specifications conform to user needs and intended use(s).

PROCESS VALIDATION: Means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

VALIDATION: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

MANUFACTURING VARIANCE: A condition to allow use of, or to perform additional processing to bring nonconforming subassembly or product into compliance, any non-conformance found during in process or quality inspection.

SPECIAL PROCESS: a special process is any production or service delivery process that generates outputs that cannot be measured, monitored, or verified until it's too late

RESPONSABILITIES MATRIX

#	SECTION	FONDERIA TARONI RESPONSABILITY	SUPPLIER RESPONSABILITY
1	**Quality System**	Ensure manufacturing of products is performed according to harmonized standards.	Maintain ISO 9001 quality system certification for products supplied to FONDERIA TARONI. Communicate to FONDERIA TARONI any change in the certification status. If the company is not certified, THE SUPPLIER has to, in any case, ensure that the manufacture / processing of the products is carried out according to the specifications sent.
2	**Audits**	Perform quality system audit of SUPPLIER as required by internal procedure.	Allow access to manufacturing areas during mutually agreed times for inspecting or auditing.
3	**Document control**	Provide and release specifications. Notification to SUPPLIER of revised product specifications.	Review specifications received from FONDERIA TARONI for acceptability into Supplier processes. Incorporate specifications into Supplier documentation system.
4	**Design Control**	Manage and execute design process for new product. Maintain DMR of Design changes. Notify to SUPPLIER of any changes to products or associated manufacturing process.	DMR manufacturing change control and maintenace. Obtain FONDERIA TARONI approval before implementing any material, component or assembly specification changes.
5	**Purchasing**	Coordinate with the SUPPLIER the selection process and supplier evaluation;	To be comply with requests and requirements of FONDERIA TARONI.

		Maintain acceptance of all components and new materials; Maintain an approved supplier list; Maintain a supplier performance management; Ensure that quality inspections on external suppliers conducted in accordance with internal procedures.	
6	**Product identification and traceability**	Responsible for establishing and maintaining the traceability of product received from SUPPLIER.	Responsible for establishing and maintaining the product tracking system by returning the internal order (ODL) required by FONDERIA TARONI to the processed batch and transport documents.
7	**Work environment**	Specify work environment requirements.	Responsible for a clean work environment.
8	**Equipment and tooling** **(if applicable)**	Share with the SUPPLIER any technical specifications or requirements required by the end customer about the equipment and tools, if applicable.	Il FORNITORE non può apportare nessuna modifica alle attrezzature senza il preventivo consenso scritto The SUPPLIER must keep the equipment under his load in good operating condition and in good condition and guarantee protection against deterioration not due to normal operating conditions. The SUPPLIER cannot make any modifications to the equipment without prior written consent.
9	**Inspection and testing**	FONDERIA TARONI reserves the right to inspect7reject any product which is defective, damaged, contaminated or otherwise not in compliance with specifications.	Implement incoming component/materials, assembly in-process and finished product inspection and testing program as appropriate to assure that product meets specifications.
10	**Inspection, measuring, and test equipment**	Specify each and all required control tools and / or any specific use requirement or method where necessary. Specify calibration and preventive maintenance requirements.	Integrate, control and calibrate the identified inspection and measuring instruments. Ensure that the instruments used for the measurements are adequate for control.
11	**Process control**	Review product manufacturing process qualifications or validations for newly designed or transfer of existing processes. Review all requalification or revalidations for all process changes.	Perform process validation for special processes. Upon request provide evidence of the process validation performed. Notify to FONDERIA TARONI any change impacting the product.
12	**Quality records**	Responsible for keeping and archiving biomedical recordings for 10 years.	Responsible for keeping and archiving biomedical recordings for 10 years. Request written permission for any destruction of recordings. Transfer the recordings to FONDERIA TARONI at the end of the trade agreement.
13	**Control of non-conforming product**	Responsible for reviewing and approve requests of shipping under concessions as appropriate.	Responsible for releasing only the product conforming to the specification or under derogation,

			subject to written authorization of FONDERIA TARONI. In case of complaint notification, the SUPPLIER is responsible for evaluating the impact on the product in stock (if present) within three days of the notification, drawing the evaluation and making appropriate arrangements on the material. The SUPPLIER is also responsible for notifying FONDERIA TARONI any non-conformance found after the shipment of the products. If applicable, the SUPPLIER may request a FONDERIA TARONI request for a derogation.
14	**CAPA**	Responsible for Issuing and Managing Non-Compliance with SUPPLIER. Responsible for reviewing the plan for corrective action and monitoring of effective implementation.	Responsible for identifying and implementing all applicable corrective and preventive actions and communicating them to FONDERIA TARONI within 30 days of receipt of the quality notice. Identify and implement the necessary corrective and preventive actions.
15	**Handling, storage packaging and delivery**	Responsible for communicating any special handling and storage conditions (if any).	Responsible for assembling, packing and storing components and products in order to prevent mixing, contamination or damage. Labelling on the outer packaging must indicate at least the product code, supply batch, work order (ODL) of FONDERIA TARONI, and the quantity contained. The SUPPLIER must ship the packaged product in such a way as to ensure integrity and cleanliness during transport. The product must not come into contact with water when stored in warehouse or in transport.
16	**Internal Quality Audits**	Responsible for ensuring internal quality system audits are conducted according approved procedures.	Responsible for conducting internal quality system audits are conducted according to approved procedures.
17	**Training**	Responsible for communicating workmanship standard, if any.	Responsible for training personnel and maintaining documents.
18	**Regulatory/Registration**	Responsible for product technical files, domestic and	Responsible for its compliance with the standard quality and safety standards.

		international registrations, and labelling controls.	
19	**Declaration of conformity**	Archiving as by internal procedures FONDERIA TARONI.	Each supply shall be accompanied by the relevant declaration of conformity which must contain at least the following information: • Name of the SUPPLIER; • Client's name; • # Orders of FONDERIA TARONI; • Product Identification; • Lot number SUPPLIER; • Quantity of product supplied; • Document approval • Date and signature of the document manager

FOR APPROVAL:

FONDERIA TARONI

ROLE	NAME	STAMP AND SIGNATURE	DATE

SUPPLIER NAME:

ROLE	NAME	STAMP AND SIGNATURE	DATE