SUPPLIER MANUAL

INNOMED MEDICAL ZRT.

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Introduction

As a MANUFACTURER of medical devices, INNOMED MEDICAL ZRT. has determined requirements for its suppliers in order to ensure and maintain the conformity of our products in accordance with Directive 93/42/EEC.

The aim of this Directive is to ensure a high-level protection of human health and safety, smooth operation of the single market and to achieve the results for which the devices are intended.

The Directive also states that the Certification Bodies during the conformity assessment of medical devices in duly justified cases may conduct an inspection on the premises of the manufacturer's suppliers and/or subcontractors to review the manufacturing processes.

In the transitional period between legislations, we wish to uphold our compliance with Directive 93/42/EEC and establish compliance with Regulation (EU) 2017/745, also known as MRD.

MDR contains further requirements that need to be applied by the medical device manufacturer. The supplier selection and control must be a fundamental part of the Manufacturer’s quality management system.

We have divided our suppliers into categories, the scope of our Supplier Quality Manual is the circle of **Critical Suppliers**. The medical devices must comply with the strict health and safety requirements set out in the legislation, so we wish to inform our suppliers about our requirements and quality control in order to minimize the risks associated with the materials and services we purchase.

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1 Definitions

Critical supplier: A manufacturer's supplier that supplies the critical processes, components or the entire device that basically determines the safety and/or performance of the medical device. (as defined in DMR)

Manufacturer: (Directive 93/42/EEC - MDD) means a natural or legal person who is responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his or her own name, regardless of whether these operations are carried out by that person himself or herself or on his or her behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under his or her own name. This shall not apply to a person which is not a manufacturer within the meaning of the first paragraph but assembles or adapts medical devices already on the market to their intended purpose for an individual patient.

Manufacturer: (Regulation (EU) 2017/745 - MDR**)** means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

2 Introduction of INNOMED MEDICAL ZRT.

The Innomed Medical Medical Development and Manufacturing Private Limited Company was founded in 1989 under the name of Innomed Kft., then in 1996, by merging several companies belonging to the group of companies, it united into a joint-stock company with a significantly increased share capital, which currently employs nearly 150 people at its headquarters in Budapest and in its factory in Esztergom.

It is a defining aspect of our guidelines that we can produce our products using the most modern technologies and the most efficient production management methods under conditions that meet both user and investor needs, while complying with strict quality assurance standards.

With our cardiology diagnostic devices, we have achieved significant domestic and foreign successes in recent years, aligned to different profession-specific needs.

Our products include both simple basic and professional ECG devices, as well as stress and 72-hour holter ECG systems.

The development of our internationally recognized clinical defibrillator began in 2002 with the acquisition of manufacturing "know-how" from the Danish company Artema, owned by Cardiac Science USA. Today, the third-generation device we have developed is one of our success products.

Our business success is based on the high quality and wide range of our products. Quality is an indispensable condition for making a purchase decision, and an essential connection between our customers and our company. Our product range, the competitiveness, the standardization and state-of-the-art production and operating environment as well as repeated orders ensure the constant customer relationships.

We meet the requirements of our customers and the applicable external regulations. To maintain compliance, we operate an integrated quality management system in accordance with ISO 9001:2015 and ISO 13485:2016 with the following scope:

„Design, development, manufacture, servicing, installation and distribution of patient monitoring, diagnostic and therapeutic electromedical devices, X-ray generators and X-ray devices and medical imaging and cardiological software.”

We are committed to maintain and strengthen our company's reputation, success, efficiency and competitiveness. Our goal is to obtain and maintain the satisfaction of our customers, sustain the conformity of our CE marked products, use state-of-the-art administrative tools and standardization and improve our processes.

3 Requirements for suppliers

3.1 General requirements (products and services)

- Traceability of raw materials/components
- Ensure compliance with product and service specifications
- Meeting the delivery time

3.2 Contractual requirements

The following points must be regulated in a contractual form between the Manufacturer and the Supplier and if justified, within the framework of a Quality Requirement, they are acknowledged by the Supplier:

3.2.1 Notification of changes

The critical supplier will notify the manufacturer of any changes before they are introduced which will affect the ability of the purchased product to meet the required purchase requirement:

- Quality management system (for example: scope, mandatory documented procedures)
- Production processes
- Change in the supplier chain
- Status of certificates

3.2.2 Announced and unannounced audits

In contractual agreements between suppliers and the manufacturer, unannounced audits may be carried out at the sites of the critical suppliers.

If a visa is required to visit the country where the supplier is located, this must be included as an annex to the contractual agreement along with an invitation issued by critical suppliers, leaving open the date of signature and the date of the visit.

3.2.3 Vigilance and post market surveillance

Provisions regulating cooperation in the event of incidents (mandatory notification; recall).

3.3 Required documented information

3.3.1 General

- Valid certificates (Quality management system, CE certificate, if applicable)
- External audit reports (certification)

3.3.2 Competence

To ensure the conformity of the quality system and medical devices where a subcontractor carries out research and development of the product supplied, the manufacturer should request evidence of their expertise/competence and qualifications.

4 Supplier selection and evaluation

The selection and evaluation of the supplier is regulated by the documented procedure of Innomed Medical Zrt. marked with FL08.

During the **selection of the supplier**, the following criteria are considered and confirmed for all suppliers:

1. What risk does the delivered product/service pose to the compliance of the medical device:
    - Performance characteristics
    - Compliance with the essential requirements
2. Ability to provide products that meet the requirements of Innomed Medical Zrt. (specifications, quality, quantity, deadline, etc.)
3. Communication (efficient, smooth…)
4. They are committed to providing quality and the appropriate professional background
5. Application of a certified quality management system
6. If available: Visit to the supplier's site

During the **annual evaluation process of our selected suppliers**, we monitor, evaluate and take into account the factors that endanger the conformity of our product, and we decide on the measures based on the results of each supplier.

Our colleagues request the following documents to carry out the annual evaluation:

- Valid Quality management system and certificates of Conformity
- Latest audit reports

5 Notification and approval of changes

The critical suppliers must notify Innomed Medical Zrt. of any changes to the delivered product or service, production system, quality management system as well as any corrective or preventive actions affecting the delivered product. This notification must be made immediately and approved by Innomed Medical Zrt. before its application.

6 Quality complaints

6.1 Inspection of incoming goods

The customer/manufacturer carries out the following checks by examining documents and quantitative controls:

- the composition of the documents obtained with the products and their conformity;
- whether the part number on the delivery note matches the part number of the ordered item,
- whether the delivered quantity is the same as the ordered (drawn) quantity;
- the packaging is correct, not opened and no damage is visible.

Based on the above checks the following measures can be taken:

- if documents related to delivery are not available, Innomed Medical Zrt. will not accept the goods,
- if the quantity of goods differs from the ordered one, it can only be accepted with the permission of the Purchase Manager, otherwise it will have to be returned,
- if the quantity delivered is less than the quantity indicated on the delivery note, the Purchasing Department will send a complaint to the Supplier for a quantity supplementation,
- if the item number does not match the item number on the delivery list, after the Warehouse manager's confirmation the Logistics Manager will initiate the return;
- in case of packaging defects or damage to the material, after the damage assessment has been made, the Purchasing division will take action.

6.2 Customer complaints, Vigilance

If Innomed Zrt. receives a customer complaint regarding a medical device placed on the market by itself, which it classifies as an incident, Innomed Medical Zrt. may request additional information about the delivered product or service used in the manufacture of the medical device involved in the INCIDENT.

Definitions mentioned above:

Customer complaint: a written, electronic communication that identifies deficiencies in the identity, quality, durability, reliability, safe use or performance of a medical device placed on the market by Innomed Medical Zrt.

Incident: (a) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;

(b) any technical or medical reason in relation to the characteristics or performance of a device for the reasons referred to in subparagraph (a), leading to systematic recall of devices of the same type by the manufacturer.

Harm: a physical injury or damage to the health of people, or any damage to the property of the user or the environment of the product

7 Recharging of costs caused by supplier fault

Innomed Medical Zrt. may charge all related costs to the supplier in accordance with the contractual provisions if the product delivered by the supplier, is non-conforming.

7.1 Logistics costs

If the Supplier has not delivered the ordered quantity within the specified deadline, the costs incurred shall be charged to the Supplier in the following cases:

- late delivery, outage or overtime due to supplier's fault.

- In case of transport damage or packaging defects, after assessing the defect and damage

The basic condition for financial charge is a complaint for the damage and the response of the Supplier to it.

7.2 Costs arising from quality

An essential condition for charging costs to the Supplier is a Report sent by the Supplier, in which the Supplier acknowledges at least partially its responsibility and identifies the cause of the defect and the relevant measures taken.

7.3 Customer costs

The costs incurred by the supplier's fault with which Innomed Medical Zrt. as its Customer was charged, shall be charged to the Supplier. The details of the costs incurred are included in the Debit Note sent to the Supplier. The Supplier must send a credit note, considering the product, costs, as well as expenses. The supplier's invoices shall not be paid until the credit note is received.

8 Quality requirements - SAMPLE

In addition to the general requirements set out in the Supplier's Manual, when ordering a particular item, we may impose specific requirements relevant to the ordered item from among the following expectations, which will be forwarded as part of the technical documentation.

The fulfillment of the quality requirements, indicated in this list is to be understood **in conjunction** with the requirements of the technical documentation.

Megnevezések / *Denominations*	**Elsőminta** *First Sample*	**Széria-gyártás** / *Serial Production*	**Leírás** / *Description*
3.1 Anyagmegfelelőségi nyilatkozat / *3.1 Declaration of Material Conformance*	*x*	*x*	
RoHS-nyilatkozat / *RoHS Declaration*	*x*		*2015/863 EU Directive*
REACH-nyilatkozat / *REACH Declaration*	*x*		
Biokompatibilitási nyilatkozat / *Biocompatbility Declaration*	*x*		
UL-megfelelőség igazolása / *UL certification*	*x*		
Gyártói megfelelőségi nyilatkozat / *CoC Conformance Statement*		*x*	
Általános mérési eredmények, adatlapok / *General measurement results, Data Sheets*	*x*		
Speciális jellemzők mérési eredményei (szigorúbb ellenőrzési, dokumentálási kötelezettség) / *Measurement results of special characteristics (requirement of stricter checks and documentation)*	*x*	*x*	
Ellenőrzési terv / *Control Plan*	*x*		
Folyamatleírás /*Process description*	*x*		
Kockázatirányítás / *Risk management*	*x*		
Gép-/folyamatképesség-vizsgálat / *Machine and Process Capability Study*	*x*		
Nyomon követés (pl. széria-, batchszámok) / *Traceability Data (e.g. Serial, Batch No.)*	*x*	*x*	
Egyéb dokumentum, tevékenység, elvárás / *Other documents, activities and requirements*			*e.g., Calibration report of measuring tools*