VascoMed
Supplier Manual

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VascoMed Supplier Manual

This Supplier Manual applies in addition to VascoMed's General Terms and Conditions of Purchase. It summarizes key aspects of our joint work and is intended to serve as a guide for our suppliers so that they can understand our requirements. This makes cooperation measurable for our suppliers, and they can align their processes with our expectations.
If individual aspects cannot be provided by the supplier in this way, we expect specific information regarding customization requests. We will take this information on board with an open mind and look at it for possible consequences for our processes.

This document is intended to describe and explain our supplier requirements, particularly with regard to the environment, data security and logistics. The Supplier Manual is a binding document. It is part of the contractual agreement between us and our suppliers. It is already valid at the pre-contractual stage and is a guide for a lasting, successful and high-quality partnership.

We strive for a high-quality and lasting partnership with our suppliers. This Supplier Manual is intended to help improve the relationship between the respective partner and us, to minimize frictional losses and to avoid additional work and costs.

1. General

1.1 VascoMed

VascoMed is a reliable partner for physicians and leading medical device manufacturers in the field of development and manufacturing of catheters and catheter systems for cardiac electrotherapy.

VascoMed's extensive expertise in the areas of plastics processing, laser welding, bonding, soldering, micromechanics, cleaning, packaging, etc. along with the very latest cleanroom technology enable the company to make products of the very highest quality as well as innovative solutions to meet the most special requirements.

VascoMed designs and manufactures in conformity with international guidelines and is certified according to ISO 13485 and MDD standards.

In order to fulfill our task, we need reliable partners. Only if all those involved along the value chain manufacture the best products at the highest technical level and at an economical cost can we be successful together over the long term in this market. We therefore see it as our responsibility to work closely with our suppliers, to exchange information in a spirit of trust and to consistently pursue potential for improvement. We want the partnership to be beneficial for both sides.

1.2 Area of application

The minimum requirements set out in this manual apply in addition to the General Terms and Conditions of Purchase (GTCP) and must be observed by all suppliers who supply or will supply us with goods and/or services (hereinafter also referred to as "Contract Products"), irrespective of where the suppliers are located or where the transfer of risk is defined.

1.3 General Terms and Conditions of Purchase (GTCP)

The GTCP are generally valid upon ordering/delivery and are binding. They shall be used as a basis with the simultaneous exclusion of other terms and conditions. Deviating provisions in individual orders or individual agreements (e.g. a framework agreement) shall always take precedence over the provisions of these GTCP.

The current version is available on our website (https://www.vascomed.com/sites/default/files/2021-07/20210618%20-

%20AEB_Vascomed_Jun21%20EN.pdf) or can be requested by e-mail to purchasing@vascomed.com.

1.4 Supplier Management

VascoMed uses the SAP Ariba source-to-procure solution to efficiently handle its strategic and operational procurement processes. In the interests of process efficiency, VascoMed expects its suppliers to register in the SAP Business Network and link the supplier account in the network with the account of BIOTRONIK Corporate Servies SE, through which VascoMed orders are also processed. Further details can be found at this link (https://www.sap.com/germany/products/business-network/suppliers/overview.html).

In order to assess and monitor supplier suitability, VascoMed reserves the right to take appropriate measures to ensure compliance with its obligations and general expectations. The following measures, among others, can be used for verification:

- Requesting the supplier to provide self-disclosure, to answer questionnaires, to provide certificates or external assessments, e.g. by ratings companies
- The possibility to carry out audits
- Designing and following development plans

2. Environmental, Social and Responsible Corporate Governance (ESG)

2.1 Supplier Code of Conduct

VascoMed takes responsibility for and is committed to adhering to the highest social, environmental and ethical standards.

For us, this means prioritizing honesty, integrity, and transparency as well as acting in accordance with applicable laws and guidelines in our day-to-day business. Compliance takes a central role and always serves as a compass for VascoMed's business conduct.

Learning about potential wrongdoing and taking appropriate corrective action, if necessary, is fundamental to meeting our commitment to ethical and legally responsible behavior. We have therefore implemented a whistleblower system that offers VascoMed employees and business partners the opportunity to report potential violations confidentially and anonymously. You can access our whistleblower system via: (https://vascomed.iwhistle.de/).

At the same time, VascoMed expects its suppliers to comply with the same principles by accepting the VascoMed Supplier Code of Conduct or by complying with their own Code of Conduct, which essentially corresponds to the contents of the VascoMed Supplier Code of Conduct.

Please consider the VascoMed Supplier Code of Conduct or your own Code of Conduct as an initiative for the entire supply chain and require at least your next-level suppliers to recognize and implement the principles.

Fundamental to the adoption of the VascoMed Supplier Code is the understanding that they must conduct all activities in full compliance with the applicable laws, rules and regulations of the countries in which business activities are conducted. The Supplier Code of Conduct can be found on the VascoMed website (https://biotronik.cdn.mediamid.com/cdn_bio_doc/bio38890/123644/bio38890.pdf).

2.2 ESG and due diligence

VascoMed is subject to strict regulatory requirements and market expectations with regard to ESG criteria and is required to provide evidence of the measures it has taken.

The requirements have an impact on the entire supply chain. VascoMed therefore requires its suppliers not only to comply with its Code of Conduct, but also to pass on the binding requirement to comply with the same principles to the next supplier level.

2.3 Environment

Suppliers must provide all deliveries and services in such a way that they comply with the current "legal provisions" at the time the product is created, regardless of where the product is created. This also includes the safety and environmental protection regulations, such as the Ordinance on Hazardous Substances and the safety recommendations of the relevant German expert bodies or professional associations.

Relevant certificates, test certificates and verifications must be supplied free of charge in accordance with the

statutory requirements. For hazardous substances, the current safety data sheet must be supplied with every delivery. The products, as well as their deliveries and services, are based on the prevailing state-of-the-art technology.

We expect all of our suppliers to be able to trace the procured intermediate goods or finished products at all stages of product creation for any production processes that are harmful to the environment or violate working conditions.

2.3.1 REACH

The supplier is obliged to fully comply with and implement the requirements arising from the REACH Regulation (EU Chemicals Regulation - Registration, Evaluation, Authorization and Restriction of Chemicals). The supplier is thus obliged to notify VascoMed of substances of very high concern (SVHC) contained in goods and to provide information. Please also note, where applicable, the weight of the components supplied.

If there is no legal obligation for the supplier to provide information, but the goods delivered to VascoMed contain substances of very high concern (SVHC), VascoMed will assume that the goods delivered without REACH information do not contain SVHC or that the legally defined maximum limit is not exceeded. In the event of changes that affect the declaration obligation, the supplier is obliged to notify VascoMed in writing within one (1) working week.

2.3.2 RoHS

If the Contract Product is an electronic device and/or an electrical component or an electronic component, the supplier is obliged to fully comply with and implement the EU directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS - Restriction of Hazardous Substances), which is regulated in Germany under the ElektroStoffVerordnung.

If VascoMed requests evidence of such Contract Products, the supplier shall deliver such evidence to VascoMed free of charge within one (1) working week.

2.3.3 Conflict materials

The supplier must take into account that the Contract Products delivered to us must not knowingly contain any conflict minerals in accordance with EU Regulation EU 2017/821 and that only sustainably produced and traded minerals (in accordance with OECD Due Diligence Guidance) are used during manufacture. According to the regulation, the supplier must also require this of its sub-suppliers along the supply chain.

We expect the supplier to provide us with written information on this within one (1) working week upon our request.

2.4 Data security

VascoMed is subject to strict regulatory requirements with regard to the security of data and information of its patients, employees, customers, and suppliers throughout the entire processing period, which result, for example, from the EU General Data Protection Regulation (GDPR) and the Network and Information Security Directive 2 (NIS2). In order to meet these requirements, suppliers must also comply with recognized and suitable data protection measures. VascoMed reserves the right to check these regularly and to request suitable evidence if necessary.

3. Order processing

3.1 Orders placed by the purchasing department and terms of payment

Orders are sent to suppliers exclusively by the purchasing department via e-mail or EDI. Procurement via order forms on the Internet and payment by credit card are the exception and require prior approval by the purchasing department on a case-by-case basis. Unless otherwise agreed, payments shall be made at our discretion within 60 days net at the middle of the month (MOM) without deduction or within 30 days with a 3% discount, provided we have no complaints about the delivery or service.

3.2 Invoicing

Invoices must always be sent electronically in a simple form by e-mail to the following e-mail address: invoice@vascomed.com

We cannot process electronic invoices that are sent to other e-mail addresses within the company.

We expect the following invoice formats (sorted by priority):

1. Electronic exchange format
2. PDF format

In order for invoices to be processed automatically, at least the following information is expected on the invoice:

- Order with purchase order
  - Order number
- Order without purchase order
  - E-mail address of the requester
  - Name of the requester

Please also note the customs requirements in section 4.3 Foreign trade law.

If essential information is missing from the invoice, it will be returned to you in future with a request to complete the missing information.

Other important rules:

- Each e-mail may contain exactly one invoice.
- Each invoice should refer to exactly one order (no collective invoices).
- The PDF files must not contain an electronic signature.
- The mandatory contents of invoices are set out in Section 14 (4) UStG [German VAT Act]. In addition, Art. 226 of Council Directive 2006/112/EC on the common system of value added tax (Directive 2006/112/EC) must be observed. Please avoid address additions that differ from this. VascoMed reserves the right to reject invoices that are not correctly stated.

4. Logistics

4.1 Terms of delivery

The transport responsibility results from the defined Incoterms (international trade clauses). Unless otherwise agreed, DDP shall apply.

In the event that Incoterm FCA has been agreed, the delivery obligation also expressly includes any customs declarations for export.

The ordered goods must be delivered in the specified condition with complete delivery documents. VascoMed reserves the right to return over-deliveries, under-deliveries or non-communicated advance deliveries in terms of quantity and date at the supplier's expense.

4.2 Notifications / Import regulations

For all deliveries from third countries, a notification by e-mail to customs@vascomed.com with the following contents is expected:

- Tracking number
- Order number
- Commercial invoice*
- Packing list incl. information on the scope of the shipment
- Information on any dangerous goods contained

Since 01 OCT 2023, there has been a ban on the import of iron and steel products if they contain (primary) materials originating in Russia. A corresponding confirmation must be sent with the advice note for the goods concerned.

*Commercial invoices must meet the requirements of Import Control System 2 (ICS2). The following information is mandatory:

- Exact description of goods
- HS code per item
- EORI number of the domestic consignee
- Incoterm (complete, with named location)

Shipping documents are required to ensure smooth shipping and customs clearance.
The packing list must contain at least the following information:

- Quantity and article number
- Order number
- Net weight per item
- Quantity of parcels and total weight
- Shipping term (Incoterm)
- Country of origin
- Shipping point/sender
- Receiver

4.3 Foreign trade law

The contractual partner shall provide any proof of origin requested by VascoMed with all necessary information and make it available without delay. The same applies to VAT-related evidence for foreign and intra-Community deliveries.

The contracting party is obliged to provide VascoMed with the following foreign trade data for each goods

delivery (including within Germany) on the delivery note or invoice:

- Country of origin
- Commodity code (HS code)
- Classification numbers:
- For Germany/EU (export list number/no. according to Annex I EC Dual-Use Regulation) if applicable
    - If the goods are subject to the US (re-)export regulations (subject to the EAR): an ECCN in acc. with EAR/ITAR
- Other national identifiers, if applicable
- If no number available then NULL message

This obligation to provide information applies to the contractual partner in the event of changes to the law and even after end of the business relationship.

The seller guarantees compliance with the provisions on the "secure supply chain", as expressed in particular in Council Regulations 2580/2001 and 881/2002. This means in particular that the contractual partner shall ensure that goods to be produced, stored or made available for transport are only produced or stored at safe operating sites, that shipping is safe and the goods are protected against unauthorized access and that the personnel involved have been trained accordingly. The contractual partner shall also ensure that any of its business partners active in its supply chain are aware of their obligations regarding this.

The contractual partner undertakes to comply with all applicable export/import regulations and any associated embargo regulations, trade bans and sanctions. For this purpose, the contractual partner shall ensure that regulations of the EU in particular and, insofar as applicable, the corresponding U.S. regulations are observed by means of suitable organizational measures.

5. Quality Management

5.1 Supplier's Quality Management System (QMS)

The supplier has established a QMS in accordance with the ISO 9001 standard. According to this standard, the supplier is permanently obliged to improve its QMS. If the supplier receives a new certificate, it must send an electronic copy of all its certificates to the responsible VascoMed supplier manager without being requested to do so.

5.2 Quality Management Agreement (QMA)

The supplier agrees in principle to enter into a QMA with VascoMed if required, due to the nature of the Contract Products supplied.

6. Supplementary Provisions

6.1 Allocation of resources

The supplier shall ensure that resources are allocated in such a way that reliable delivery of the Contract Products to VascoMed is possible. It is obliged to maintain an appropriate stock of goods at all times, which always exceeds the delivery quantity. This inventory must be ensured at all times — even during maintenance periods. In addition, the supplier undertakes to provide six (6) months' advance notice of any maintenance period.

6.2 Relocation of the production facility

In order to avoid delivery bottlenecks, the supplier must provide at least twelve (12) months' advance notice of any relocation of a production facility and its subsequent steps to maintain delivery capability.

6.3 Contingency plan

The supplier must draw up and implement a contingency plan within its organization to be used in the event of disruptions that affect the value chain and the ongoing supply of Contract Products to VascoMed. The contingency plan is intended to help ensure delivery capability.

Disruption can be:

- Relocation of machines and tools
- Delays or damage to the delivery
- Nonconformities
- Breakage damage to tools or machines
- Disruptions to deliveries from subcontractors
- Computer/network problems

Possible measures could be:

- Building up safety stocks
- Provide/qualify alternative production options
- Know alternative sources of supply for primary materials
- Sufficient IT security measures

- Flexible capacities to ensure delivery capability via short-term rework (weekend work, shift work, etc.)
- Communication matrix with contact persons and representatives in different departments

The supplier must further develop the contingency plan and implement it in its operations in order to guarantee smooth operations in the event of such disruptions. Upon request the supplier shall submit its contingency plan to VascoMed.
Should the above-mentioned disruptions occur, VascoMed must be informed immediately by the supplier in order to guarantee effective cooperation and appropriate delivery in good time.