

# MEDICAL DEVICE DISTRIBUTION TERMS

## PREAMBLE

BIEGLER GmbH is engaged in the design, manufacture, and sale of medical devices ("Products").

These Medical Device Distribution Terms ("Distribution Terms") establish the regulatory compliance requirements under which any distributor, importer, or purchaser handles Products in compliance with all applicable medical device laws and standards.

These Distribution Terms apply automatically to all purchases and distribution of medical devices manufactured by BIEGLER GmbH, registered in the Commercial Register under the number FN 98605 h, with its headquarters located in Allhangstrasse 18a, 3001 Mauerbach, Austria ("Manufacturer").

## DEFINITIONS

The parties hereby agreed to use definitions in the following meanings:

**"Distributor"** means any natural or legal person in the supply chain, other than the Manufacturer, or, if applicable, the Importer, that makes a device available on the market, up until the point of putting into service.

**"Falsified device"** refers to any medical device that is falsely represented in terms of its identity, origin, or compliance with regulatory requirements, including forged or altered certificates, licenses, or labeling from any relevant regulatory authority.

**"Importer"** means any natural or legal person established in the Territory that places a device from a third country on the Territory market.

**"Products"** means Manufacturer's products that are placed on the market or made available on the market, namely medical devices and their accessories.

**"Territory"** means the geographical area, where Products are distributed, as defined in the respective order.

## DISTRIBUTOR'S OBLIGATIONS

**Distribution:** Make Products available on the market in the context of their activities, act with due care in relation to applicable regulatory and statutory requirements.

**Compliance:** Verify that the Products comply with the applicable regulatory and statutory requirements.

**Reporting:** If the Distributor considers or has reason to believe that a Product which the Importer has made available on the market is not in conformity with the applicable regulatory requirements shall immediately inform the Manufacturer and, where applicable, its Authorized Representative and the Importer.

**Cooperation:** Cooperate with the Manufacturer and, where applicable, the Importer, and with competent authorities to ensure that the necessary corrective action to bring that Product into conformity, to withdraw or to recall it, as appropriate, is taken. Where the Distributor considers or has reason to believe that the Product presents a serious risk, they shall also immediately, but not later than the local regulatory requirements inform the competent authorities of the country in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken. Furthermore, they shall inform the Manufacturer immediately, but not later than 1 (one) business day.

**Complaint Forwarding:** Distributor shall furthermore forward any information they may receive related to complaints, suspected incidents related to a Product, suspected Falsified Device to the Manufacturer and its Authorized Representative in a timely manner.

**Record Keeping:** Distributor is obliged to keep comprehensive records on the Products delivered, i.e. to maintain the Products traceability. The records must contain adequate information to allow a complete and fast withdrawal of the Products from the Territory. Distributor must store all records for at least 10 years from the date of the transfer protocol or for a longer period if required by applicable law.

**Complaint Register:** Keep a register of complaints, of non-conforming Products and of recalls and withdrawals, and keep the Manufacturer and, where applicable the Importer and Authorized Representative informed of such monitoring and provides them with any information upon their request.

**Authority Requests:** Upon request by a competent authority, provide all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a Product.

**Authority Cooperation:** Cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by Products which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the Product or, where that is impracticable, grant access to the Product.

**Inventory:** Maintain an adequate inventory of Products to meet Manufacturer demand.

**Storage and Transport:** Ensures that, while the Products are under their responsibility, storage or transport conditions do not jeopardize its compliance with the applicable regulatory requirements and shall comply with the conditions set by the Manufacturer, where available.

**Legal Compliance:** Comply with all applicable laws and regulations relating to the marketing, sale, and distribution of the Products.

**Sales Reporting:** Provide regular reports on sales performance, inventory levels, and market conditions.

**Marketing Claims:** Avoid making any unauthorized representations, unauthorized marketing claims or warranties about the Products or any claims that are not part of the instructions for use. Should the Distributor utilize any additional marketing claims, such use shall be permitted only upon obtaining Manufacturer's prior written consent.

**Staff Training:** Ensure that all staff involved in the sale of Products are adequately trained.

**No General Distribution Rights:** The Distributor acknowledges and agrees that it is not granted any general distribution rights with respect to Manufacturer's products. This transaction is a one-time, limited-purpose sale of the specific Products purchased by the Distributor, and does not confer upon the Distributor any continuing rights or authority to sell, market, or distribute Manufacturer's Products beyond the scope of this particular transaction. The Distributor shall have no authority to act, and shall not hold itself out, as an agent, representative, or authorized general distributor of Manufacturer in any capacity.

## IMPORTER'S OBLIGATIONS

The additional provisions set forth herein shall apply in instances where Distributor also assumes the role of Importer.

**Device Compliance:** The Importer ensures that only devices which comply with all applicable local laws and regulations are placed on the market. The Importer is responsible for verifying that the devices meet all relevant conformity requirements prior to making them available for sale or distribution within the applicable jurisdiction.

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**Importer Labels:** Importer indicates on the device or on its packaging or in a document accompanying the device its name, registered trade name or registered trademark, their registered place of business and the address at which they can be contacted, so that their location within the Territory can be established. Importer ensures that any additional label does not obscure any information on the label provided by the Manufacturer.

**Labelling and Instructions:** Importer ensures that the device is labelled in accordance with the applicable regulatory requirements and accompanied by the required instructions for use (IFU) appropriate for the Territory.

**UDI:** Importer ensures that the UDI has been assigned by the manufacturer in accordance with the applicable regulatory requirements.

**Authorized Representative:** Importer ensures that an Authorized Representative is available and registered with the applicable authority.

**Document Retention:** Importer, for the period defined in the applicable regulatory requirements, keeps a copy of the product-related documents such as EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with the applicable regulatory requirements.

**Additional Requirements:** Where applicable and required:

Importer cooperates with competent authorities, at their request, on any action taken to eliminate or, if that is not possible, mitigates the risks posed by devices which the Importer has placed on the market.

Importer, upon request by a competent authority of the country in which the Importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

## APPLICABLE REGULATORY REQUIREMENTS

**Inspection Rights:** Distributor is committed to provide rights to inspect and audit the facilities of Distributor's or its subcontractor's and records for Notified Body and/or National Competent Authority.

**Certificates:** The Distributor shall provide the Manufacturer with a copy of all relevant certifications applicable to the services rendered, where such certifications are available. These may include, but are not limited to, ISO 13485, ISO 9001, ISO 27001, and ISO 17100, depending on the nature of the services provided. Such certifications must cover the same scope as the services performed under these Distribution Terms. The certificates must be issued by a notified body or certification body duly accredited by the respective national accreditation authority in accordance with applicable regulations and standards.

**Certificate Status Updates:** The Distributor is further obliged to promptly notify the Manufacturer in writing of any changes affecting the status of these certifications, including but not limited to certificate renewal, changes in scope, suspension, or withdrawal.

## INTELLECTUAL PROPERTY

**Intellectual Property Rights:** The Distributor acknowledges that all rights, title, and interest in the Intellectual Property remain the sole property of the Manufacturer.

**Modifications:** The Distributor shall not modify, reverse engineer, or create derivative works from the Products.

**Restriction:** Distributor may only use Intellectual Property Rights owned by Manufacturer or Manufacturer Confidential Information for the purpose of performing Distributor's obligations under this Agreement.

## CONFIDENTIALITY

**Mutual Confidentiality:** Both parties agree to maintain the confidentiality of all Confidential Information disclosed under these Distribution Terms.

**Third-Party Disclosure:** Confidential Information shall not be disclosed to third parties without the prior written consent of the disclosing party, except as required by law.

## INDEMNIFICATION

**Distributor Indemnification:** Distributor agrees to indemnify BIEGLER and hold it harmless from any liability, loss, expense, cost, claim or judgment (including reasonable attorneys' fees) arising directly out of: (a) Distributor's breach of these Distribution Terms (b) Distributor's breach of the warranties provided in the Biegler Sales and Delivery Terms.

**Limitation of Liability:** BIEGLER shall not be liable for any damages, including without limitation, direct or indirect consequential damages or lost profits, unless Distributor can establish that such damages are the result of the BIEGLER's willful misconduct or gross negligence except in cases regarding product liability under applicable law.

## GENERAL PROVISIONS

**Governing Law:** The rights and obligations of the Parties in connection with the Distribution Terms and any purchase of the products shall be governed exclusively by the provisions of Austrian law. The application of the United Nations Convention on Contracts for the International Sale of Goods is herewith excluded.

**Force Majeure:** Neither party shall be liable for delays caused by circumstances beyond their reasonable control. Force Majeure Clauses in the Sales and Delivery Terms apply.

**Notices:** Any notice required or permitted under these Distribution Terms shall be in writing and delivered to the addresses specified below.

All notices, requests, requirements or any other communication hereunder shall be executed in English, and shall be sent by e-mail to office@biegler.com. In urgent matters, contact shall be made via phone: +43 1 9792105.

## ACCEPTANCE

By purchasing products for which the Manufacturer is the legal manufacturer, the Distributor hereby acknowledges and accepts these Distribution Terms in the absence of a separately executed agreement.

These Terms are deemed accepted upon (a) Acceptance of purchase order/invoice referencing these Terms, (b) Taking delivery of Products, or (c) Continued distribution of Products after notification of these Terms.

## CONTACT INFORMATION

**BIEGLER GmbH**  
Allhangstrasse 18a  
3001 Mauerbach, Austria  
www.biegler.com

**Contact:**  
E-mail: office@biegler.com  
Phone: +43 1 9792105