

Dear valued customer

We thank you for your order of BÜHLMANN products.

Please take note of the following **Terms and Conditions**, which are valid for this business contract. They are accepted and become legally binding with the acceptance of your BÜHLMANN offer (**pro-forma invoice**).

### **Payment Terms and Conditions**

All prices for direct deliveries are EXW Basel (International shipments are sent freight collect and transport costs are charged directly to the customer by the transport company). International orders require payment in advance until a credit history has been established. Payment terms are net 30 days.

Supplied products remain in the property of BÜHLMANN until completion of payment(s).

### **Regulatory Requirements**

Customer confirms to have obtained all necessary licenses, permits or other local regulatory clearances required by the law of the Territory where the product is supplied to for the import, promotion, marketing, supply, sell and use of the BÜHLMANN Products, including, if applicable, the license for handling radioactive material (Iod-125) and customs authorisations.

In case of IVD products, customer takes note of the following obligations:

- (i) Keeps appropriate up-to-date and accurate records to trace the IVD Products delivered from customer to end-user by serial or lot number and, if available, UDI number. Such records must be stored for the shelf-life of the product and at least the following ten (10) years after the expiration date of the product, and, if requested, be presented to its national authorities, BÜHLMANN or Swissmedic;
- (ii) Keeps the required records and report complaints and investigations for input to the corrective & preventive action system as well as records of adverse events and recalls for the duration of the product life cycle and at least the following ten (10) years after the last device of the IVD Product has been placed on the market, as communicated by BÜHLMANN. Documented procedures for adverse events must meet the medical device requirements for problem reporting;
- (iii) Translates all necessary documents required by CE regulations and local requirements in the requested national languages and manage its distribution to end-user customers, if they are not packaged in the IVD Product packaging. BÜHLMANN shall provide to customer without charge the necessary English language technical and other data sheets. Copyright in all such materials and documents shall remain with BÜHLMANN and BÜHLMANN reserves the right for a final check and release of such documents;
- (iv) Ensures to have a quality management system in place that includes procedures which ensure that the translation of information is accurate and up-to-date;
- (v) Ensures that any claim presented in Customer's promotional material is supported by appropriate validation data;

(vi) Not changes any part or aspect of a IVD Product which is validated and CE marked as a combination (e.g. change applications, sell non-system reagents or provide application advice without proper validation or sell consumables not manufactured or authorized by BÜHLMANN) without authorization by BÜHLMANN;

(vii) Follows BÜHLMANN's instructions for installation, preventive maintenance, market withdrawal, recall;

(viii) Informs BÜHLMANN without delay, but within not more than five (5) days of received complaints or reports from healthcare professionals, patients or users about adverse events, any malfunctions which may have led to or could lead to an adverse event should the malfunction recur as well as out-of-specification events related to a Product and follow all instructions given by BÜHLMANN as reaction to the reported adverse event or malfunction;

(ix) Indicates on the IVD Product or on its packaging or in a document accompanying the IVD Product their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer; and

(x) If customer considers or has reason to believe that an IVD Product which has made available on the market is not in conformity with this Regulation shall immediately inform BÜHLMANN. Customer shall co-operate with BÜHLMANN to ensure that the necessary corrective action to bring that Product into conformity is taken.

BÜHLMANN shall have access to customer records as required by regulatory obligations of BÜHLMANN. These records must be adequate to permit a complete and rapid withdrawal or recall of Products from the market. Customer shall provide BÜHLMANN with all details requested, without limitation, including customer name, address and contact details, batch or lot numbers, and quantities sold, in order to facilitate traceability of Product from customer to end user.

Customer shall co-operate with BÜHLMANN in the recall of any of the Products for safety checks or modifications.

Customer shall ensure that, while the Product is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.

### **Claims and Returns**

All incidents of shortage, breakage, any other product damage or shipping errors have to be reported within five days of receipt of goods. BÜHLMANN cannot honor any claims reported after the five-day period. In the event of a claim for lost, delayed or damaged shipments, the customer must file the claim with the carrier and not hold BÜHLMANN responsible. BÜHLMANN assumes no liability for loss or delay caused by strikes, accidents, delays of carriers, acts of God, or other causes beyond BÜHLMANN's control.

No product may be returned to BÜHLMANN unless prior written authorization and shipping instructions obtained from BÜHLMANN logistics department. Returns may be subject to a restocking fee. Some products, due to their biological nature, are considered final sales and, therefore, cannot be returned.

The contract between the company and the customer shall be deemed to have been made in Switzerland and shall be governed in all aspects to Swiss law. The customer shall submit to the jurisdiction of the Swiss court.

**Guarantee**

Unless stated otherwise and except for Iod-125 products, Products from BÜHLMANN are usually guaranteed to perform as BÜHLMANN claims for a minimum of 5 months after shipment from our warehouse, if they were handled and stored properly and according to BÜHLMANN instructions.

BÜHLMANN kits with Iod-125 radioactive components have a shelf life of approximately 50 days from the day of new labelling. Since fresh tracer is prepared every month, kits will not be shipped with less than 20 days of shelf life remaining, whenever possible. For Iod-125 kit orders please refer to the actual labelling schedule. Due to the physical properties of Iod-125 we do not recommend to use these kits after the expiration date of the tracer.

**BÜHLMANN Customer Support**

Please use our online enquiry form or contact us at +41 61 487 12 12 (phone) or +41 61 487 12 34 (fax).

To facilitate enquiries and support quick and reliable feedback, please keep ready the product code, lot number, expiry date and a specification of your request.

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