

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 sales contract for direct sales and distributors without a valid Distributor Agreement. They are accepted and become legally binding with the acceptance of your BÜHLMANN offer (**pro-forma invoice**). Please note, that for BÜHLMANN distributors with valid a Distributor Agreement the Terms and Conditions of the specific Distributor Agreement apply.

Sales Contract

A BÜHLMANN sales contract always includes an “offer” by the seller (BÜHLMANN) and an “accept” by the buyer of the product (Customer). A sales contract always includes the parties (BÜHLMANN and Customer), the product and the price.

Payment Terms and Conditions

All prices for direct deliveries are EXW Schönenbuch according to Incoterms 2020 (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 customs authorizations.

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 must 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, riots, pandemics, delays of carriers, acts of God, or other causes beyond BÜHLMANN's control ("Force Majeure").

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.

Warranties

BÜHLMANN warrants that its Products are in conformity with BÜHLMANN's specifications and are suitable for registered use.

BÜHLMANN's liability in respect of any order or otherwise shall in no case exceed the obligation to replace any defective Product. These exclusions and limitations on damages shall apply regardless of how the loss or damage occurred (breach of contract, tort or otherwise).

Except in case of damage or defect attributable to BÜHLMANN, the customer shall not make any claims against BÜHLMANN for any damaged or defective Products or parts.

Subject to Product liability, BÜHLMANN shall not be liable for an indirect, incidental and consequential loss or damage; any loss or damage arising from business interruption, loss of profits, loss of revenue, loss of use of any property or capital, loss of anticipated savings etc.

Unless stated otherwise the 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 Sales Support

Please use our online enquiry form or contact us at +41 61 487 12 12 (phone) or via email info@buhlmannlabs.ch.

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.

The contract between BÜHLMANN 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.

Update: April 17th, 2023