

General Delivery Terms and Conditions Addendum for Medical Products

Complementary to our General Terms and Conditions, the following provisions shall apply for this order:

- a) BBC Cellpack Technology AG is the supplier of this product and not the distributor or manufacturer in accordance with Regulation (EU) 2017/745 on medical devices - Medical Device Regulation (MDR) or the Medical Products Act. The ordering customer is responsible for compliance with the guidelines and laws applying for this product.
- b) BBC Cellpack Technology AG does not conduct any conformity assessment procedures and does not issue a CE conformity declaration.
- c) BBC Cellpack Technology AG manufactures these products according to the drawings and documents made available by the ordering customer taking into consideration any possible present quality assurance agreement or other arrangement agreed to with the ordering customer. Further, the ordering customer is responsible for communicating to BBC Cellpack Technology AG all information necessary for the orderly execution of the order.
- d) The material to be used shall be specified by the ordering customer.
- e) The necessary information, such as, for example, certificates, identification (item, type, process, etc.), packaging, labels, shipping, etc. shall be specified by the ordering customer.
- f) BBC Cellpack Technology AG, with advance notice, shall give the ordering customer the possibility to check the manufacturing process or carry out an audit at any time. Unannounced audits by a notified body are reserved.
- g) The inspection planning and specifications will be established for each product after consulting with the ordering customer.
- h) Unless otherwise agreed, the ordering customer is responsible for the technical documentation for this product as stipulated in Regulation (EU) 2017/745 on medical devices - Medical Device Regulation (MDR) or the Medical Products Act.
- i) Unless otherwise agreed, BBC Cellpack Technology AG shall retain the specifications and verification documents for 30 years (after the manufacture of the last product).
- j) The reporting and registration requirements with respect to the authorities as stipulated in the Medical Products Act or the Medical Products Monitoring and Reporting System are the responsibility of the ordering customer.
- k) The products manufactured or delivered by BBC Cellpack Technology AG are neither sterile nor sterilely packaged and not permitted for direct use as instruments or implants with body contact. Unless otherwise agreed with the customer.
- l) The traceability of products can only then be guaranteed when the products can be clearly identified by BBC Cellpack Technology AG.