



**Product/Service Purchased**

**Applicable PO Clause Codes**

<b>Raw Materials, Hardware, Chemicals, Other Materials and Services</b>	<b>C01 through C17 apply.</b>
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Clause Number	Title	Requirement
C01	Quality System	Supplier shall establish and maintain a Quality System acceptable to Breathh, for the goods and/or services purchased under this purchase order. As a minimum, the supplier's Quality System must meet the requirements of ISO13485 and ISO9001 or better.
C02	Supplier Furnished Material	Supplier shall submit Chemical and Physical test reports in accordance with the latest material specifications and revision. Distributors must provide a certification verifying the materials traceability to the Mill test reports when supplied.
C03	Sub-Contractor Flow Down	Supplier is required to flow down the requirements of this purchase order, including terms and conditions to the Supplier's subcontractors. Flow down of key characteristics is required when specified on the face of purchase order.
C04	Record Retention and Disposition	As a minimum, the Supplier is to retain records for at least 10 years from the date of shipment under each applicable order for all products/part numbers unless otherwise specified in the order. In special circumstances, the purchase order will identify the actual required number of years that the records should be maintained. After the minimum retention period is achieved, suppliers may disposition the records as archive or destroy at their discretion.
C05	Parts Identification	The Supplier is to identify parts in accordance with purchase order requirements.
C06	Nonconforming Product/Corrective Action	The Supplier is to notify Breathh, Inc. of any Nonconforming product prior to shipping product and obtain approval for disposition of any nonconforming product. In addition, the Supplier will maintain a system of handling non-conformances and corrective actions.
C07	Packaging Protection	Supplier to package parts in a manner that will protect parts from any kind of damage. No metal-to-metal contact is ever allowed. In special circumstances, the purchase order may specify the manner the parts are to be packaged.
C08	Material Safety Data Sheets	All materials supplied on this order must be accompanied by the applicable Safety Data Sheet
C09	Certificate of Conformance	A certification is required, stating that all the products or services meet the contractual or purchase order requirements. The certificate must list the part number and all the applicable process specifications, including up to date revision levels.
C10	Verification on Supplier's Premises	Verification of product on supplier premises by Breathh or its customers, does not remove the obligation to provide conforming products and shall not be used as the organizations evidence of conformity.
C11	Right of Entry	Breathh, our customers, and/or any applicable regulatory authority reserve the right to access the supplier's applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records. Reason for access may include inspection of the item on order, status of the item, or reviewing quality records pertaining to the purchase order in question.
C12	Quality Awareness	Suppliers Personnel must be made aware of: <ul style="list-style-type: none"> <li>• their contribution to product or service conformity;</li> <li>• the importance of ethical behavior.</li> <li>• the importance of complying with applicable environmental laws &amp; regulatory requirements.</li> </ul>

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Clause Number	Title	Requirement
C13	Control & Monitoring Requirements	Supplier must maintain a Quality Level $\geq 90\%$ and an OTD level $\geq 90\%$ . If levels drop below target, supplier will be notified and may be placed on conditional status or disapproved if not corrected
C14	Change Notification	Supplier is to notify Breathh of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval.
C15	Shelf Life Materials	The supplier provides the manufacturing date, shelf life, and expiration date for all limited shelf-life items under this order. All items will have 75% or more of their shelf life remaining at the time of shipment to Breathh. All items are packaged, labeled and transported per their applicable regulatory requirements.
C16	Counterfeit Prevention	Supplier must have a process in place to detect and prevent the use of counterfeit parts/materials. The holder of the Breathh Purchase Order must be the Original Equipment (Component) Manufacturer (OEM) of the product or the OEM's Authorized Distributor with traceability to the OEM. Authorized distributors shall provide certification to OEM approved distribution. Or provide evidence of certification, or approval from the appropriate OEM of the product supplied to Breathh.
C17	Calibration Supplier	The calibration supplier shall be accredited to ISO17025. All measuring and test equipment shall be calibrated in accordance with ANSI/NCLSL Z540.3 and traceable to NIST.