**Intertek ISO 18562 Quotation Request Form**

Form submission notes:

* A separate form is required for each unit to be tested.
* A copy of the device user's manual should be provided where applicable.
* Please provide any relevant supporting biological evaluation information.
* Completed forms and supporting documents can be sent to your Intertek Account Manager. If you do not have an Account Manager, submit via email to icenter@intertek.com with “Medical VOC Quote Request” in the subject line.

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| **Name:** |   | **Company:**  |   | **Email:** |   |
|  |  |  |  |  |  |  | **Phone:** |  |
|  |  |  |  |  |  |  |  |  |  |
| **General Device Information** |   |   |   |   |   |   |   |
| **Device name** |  | **Part No.** |   |
| **Device function (e.g. ventilator, CPAP, etc.)** |  | **Flow style** | [ ]  Continuous | [ ]  Pulsed |
| **Does the device require emergency use authorization or the standard device approval process?** |   |
| **Does the device contain a single flow path or are multiple flow paths possible based on device settings?** |  |
| **What are the intended patient populations for your device? Check all that apply.** | [ ]  **ALL** | [ ]  Premature Neonate[ ]  Infant | [ ]  Small Child[ ]  Child | [ ]  Adolescent[ ]  Adult |
| **What is the *cumulative* intended use duration of the device?**  |  [ ]  Limited (≤24 hrs) | [ ]  Prolonged (1-30 days) | [ ] Long-term (>30 days) |
| **What is the maximum *daily* use duration (in hours)?** |   |
| **Please specify the minimum clinically relevant flow setting (volumetric flow in L/min preferred).** |   |
| **Please specify the maximum clinically relevant flow setting (volumetric flow in L/min preferred).** |   |
| **Please specify the maximum clinically relevant ambient operating temperature.** |   |
| **Does the unit draw air from the surrounding environment or from a plumbed source?** Please list all air inlet/outlet connections. |  |
| **Does the unit require a gas other than air for operation (e.g. oxygen)?** | [ ] Yes | [ ] No |
|  - If so, please provide required gas, supply pressure, concentration and/or flow rate. |   |
| **Please list all device components in contact with the gas flow.** |  |
| **Additional notes regarding your device (e.g. setup or operation notes).** |  |
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| **Do you require consulting services to determine the scope of testing?** |   | [ ] **Yes**  | [ ] **No** |
| Intertek's consultants can help you navigate regulatory requirements and advise the appropriate testing and test conditions for your medical device or accessory. If you do not have a working test protocol established, we advise working with our consultants to ensure the scope of testing will meet the expectations of the applicable regulatory bodies. |
| **Special Considerations:** |  |
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| **Do you need a toxicological risk assessment per ISO 18562-1?** |   |   | [ ] **Yes**  | [ ] **No** |
| Our expert team of toxicologists will review analytical test data to determine the patient exposure levels and evaluate the toxicological risk for each intended patient population. |
| **Special Considerations:** |  |
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| **Do you require Particulate Matter testing to ISO 18562-2?** |   |   | [ ] **Yes**  | [ ] **No** |
| Particulate matter is measured as an air concentration in µg/m3. By default, measurement is by laser photometer. Gravimetric sampling is utilized for devices with a maximum flow rate greater than 2 L/min or by request. |
| **Do you require inorganic gas measurement (i.e. carbon monoxide, carbon dioxide & ozone) as well?** | [ ] **Yes**  | [ ] **No** |
| **Special Considerations:** |  |
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| **Do you require VOS testing to ISO 18562-3?** |   |   |   |   | [ ] **Yes**  | [ ] **No** |
| Air sampling and analysis are performed according to ISO 16000 parts 3, 6, 9 & 11 with analysis by thermal desorption GC-MS and UV-Vis HPLC. All observed non-target compounds are quantified with a reporting limit of 2 µg/m3. |
| **Have any target compounds been identified for analysis by a prior risk assessment?** | [ ] **Yes**  | [ ] **No** |
| **Please list all target compounds, including CAS #.** |  |
| **Special Considerations:** |  |
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| **Do you require leachate testing for liquid condensate per ISO 18562-4?** | [ ] **Yes**  | [ ] **No** |
| A full analysis of leachables observed in the condensate is performed to identify the compounds present as well as the toxicological risk of each.  |
| **Is any liquid applied for device operation?** | [ ] **Yes**  | [ ] **No** |
| If yes, please describe. |  |
| **Is the device used to deliver medication to the patient?** | [ ] **Yes**  | [ ] **No** |
| If yes, please describe. |  |
| **Do you have chemical characterization data for biocompatibility assessment according to ISO 10993-18?** | [ ] **Yes**  | [ ] **No** |
| **Do you need chemical characterization for biocompatibility assessment according to ISO 10993-18 for any parts or the whole device?** | [ ] **Yes**  | [ ] **No** |
| **Special Considerations:** |  |