**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](mailto:icenter@intertek.com) with “Medical VOC Quote Request” in the subject line.

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| **Name:** |  | | | **Company:** |  | | | | **Email:** |  | | | | | |
|  |  | |  |  |  |  |  | | **Phone:** |  | | | | | |
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| **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:** | | |  | | | | | | | | | | | | |