QA.APP.GEN-65.01

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| **Medical Gas: Technical Questionnaire** |

This questionnaire is used to collect information from vendors with regards to Medical Gas.

***Instructions:***

*Fill out the information that is applicable to the product. Complete one questionnaire per product presentation.*

*Complete the fields in this questionnaire as applicable.*

* *Tick or place an X in any of the blocks that are true/applicable.*
* *Add rows to tables to include requested information. Alternatively, you may attach information in a separate sheet using the same format requested.*

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# Applicant Information

*The information in this questionnaire can be shared confidentially between USAID and its implementing partners, WHO and The Global Fund for procurement purposes. If approved, the approval (including product identification, manufacturing sites, approved specifications, test methods and publicly available information) may also be shared with other procurement agencies. If applicant has any objections, mark an X in the box:*

objection to sharing information between USAID and implementing partners, and/or other organizations.

|  |  |
| --- | --- |
| Request for Proposal Number |  |
| Questionnaire Submission Date *(DD/MON/YYYY)* |  |
| Company Name (Supplier) |  |
| Physical address |  |
| Postal address |  |
| Telephone number |  |
| Fax |  |
| Website |  |
| e-mail |  |
| Link to product | *(Select all that apply)*  Marketing license holder  Distributor/wholesaler  Manufacturer  Other (Specify): |
| Provide contact information for each of the following: | |
| Technical Specifications and Quality Assurance |  |
| Regulatory and patent |  |
| General Inquiries |  |

# Product Identification

|  |  |
| --- | --- |
| Medical Gas Establishment Type | **Transfiller**: *A firm that manufactures medical gas by transferring the gas, either in a liquid or gaseous state, from a larger container into smaller containers, either high-pressure cylinders or cryogenic vessels, are filled from larger containers (in a process known as “cascading”) or from permanently mounted tanks.*  **Air Separation Unit:** *These units separate atmospheric air into its constituent gases of oxygen, nitrogen, and argon through a process of pre-cleaning, compression, cooling, and fractional distillation of liquefied air.*  **Chemical Synthesizer or processor:** *sites that produce bulk nitrous oxide or carbon dioxide.* |
| Product Identification Number (including any variant) |  |
| Brand name |  |
| Generic name of the product |  |
| Sterility |  |
| Purity |  |
| Standard Claimed |  |
| Intended Purpose |  |
| Level of Use | Health post;  Health centre;  Hospital; regional hospital,  Emergency vehicles;  Home care. |
| Shelf-life (months) |  |
| Storage Conditions |  |
| Packaging Type | Medical gas cylinder  Medical gas cylinder, portable  Oxygen Plant (central oxygen supply system)  Bulk liquid oxygen generated off-site and stored in a large tank and supplied through a central pipeline system. |
| Country Regulatory Registration |  |
| Manufacturing Site |  |
| Distributors |  |

# Documentation request

## Supplier Documentation

Attach a copy of Business Certificate of Registration issued by the country of registration; and including all sites. The Scope of the Certificate of Registration shall include appropriate information to identify the product.

Attach a copy of valid ISO 13485: latest version certificate or GMP certificate

Attach a copy of valid ISO 14001: latest version certificate

## Manufacturer Documentation

Attach a copy of valid GMP Certificate

Attach a copy of Certificate of Manufacture issued by the country of origin

## Product Documentation

Attach a copy of Certificate of Analysis (example)

Attach a copy the Product Datasheet

Attach a copy of the Label Artwork

## Regulatory and Licensing Documentation

Provide proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product’s risk classification (e.g. by a founding member of IMDRF - EU, USA, Canada, Australia, Japan).

Attach a copy of regulatory registration in the countr(ies) of intended use

Attach a copy of regulatory registration in export country