**Please complete and forward electronically to Clinical Product Co-ordinator (CPC), or equivalent, within a PEHNZ affiliated Health Care provider. Supplier will be contacted prior to further promotion.**

|  |  |
| --- | --- |
| **Date:** |  |
|  |  |
| **Product Line:**  (e.g. Urine Catheters**)** | | | **Code:**  *(If more than 1 please list*  *separately)* | **Price:** |
| **Description:** | | | | |

|  |  |
| --- | --- |
| **Manufacturer/Brand Name:** | **Country of Manufacture:** |

**SUPPLIER DETAILS:**

|  |  |  |  |
| --- | --- | --- | --- |
| Agent: | Distributor: | | **Manufacturer:** |
| **Company Address:** | | | | |
| **Representative Name:** | | **Signature**:(if requested) | | |
| **Email:** | | **Phones – Mobile/Office:** | | |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Is product new to New Zealand? | | | | Yes | | No | | |
| Does the product or packaging contain Latex, DEHP, or Chlorhexidine? | | | | N/A  Latex  DEHP  Chlorhexidine | | | |
| Is this a reusable or single use item? | | | Reusable | Single | | Single patient | | |
| Is the product supplied clinically clean or sterile? | | | | Clean | | Sterile | | |
| Expected shelf life at manufacture: | | | | Years: | | Months: | | |
| Is this product or any of its components derived from human or animal  tissue? (Further clarification may be requested) | | | | Yes | | No | | |
| **COPY OF ALL RELEVANT** **COMPLIANCE AND REGULATORY CERTS MUST BE PROVIDED (electronically)** | | | | | | | | |
| Medsafe Number (WAND or Medicine File Number) | Yes | Number  Copy Supplied | | | No  Exemption classification | | | |
| Certification Type: **CE** | | **No.** | | | Copy supplied  *(English version)* | | | |
| Certification Type: **FDA** | | **No.** | | | Copy supplied | | | |
| Certification Type: **TGA (Australian)** | | **No.** | | | Copy supplied | | | |
| ISO | | | | | Copy supplied | | | |
| GMP | | | | | Copy supplied | | | |
| GS1/UNSPSC Code | | | | | Copy supplied | | | |
| GMDN Code | | | | | Copy supplied | | | |
| Sterilisation compliance | | | | | Copy supplied | | | |
| Letter of conformity | | | | | Copy supplied | | | |
| Material Safety Data Sheet       (NZ Compliant) | | | | | Copy supplied | | | |
| User manual, operating manual, instructions for use as applicable | | | | | Copy supplied | | | |
| Information on suitable cleaning solutions **MUST** be provided where applicable to use of equipment or accessories, to ensure they meet user/customer Infection Prevention and Control policies. | | | | | Copy supplied | | | |
| Any other supporting compliance data eg NZS, AS/NZS, IEC, EEC | | | | |  | | | |
| Is this product part of a contract with any purchasing group in New Zealand? | | | | | Yes | | No | |
| Purchasing Group: PHARMAC DHB/hA NZHP Other (please state) | | | | | | | | |
| Is this product in use in other hospitals in New Zealand? | | | | | Yes | | No | |
| Please state reference sites within NZ: | | | | | | | | |

**Health and safety:**

|  |  |  |
| --- | --- | --- |
| Does the product or packaging contain any Hazardous Substances? | Yes | No |
| Does the product or packaging contain Sharps? | Yes | No |
| Are there any Manual Handling issues? | Yes | No |
| Are there any safety precautions or contra-indications in regard to the use of this product? | Yes | No |
| If yes to any of above, please describe: | | |

**Training:**

|  |  |  |
| --- | --- | --- |
| Will your company be providing Training for this product? | Yes | No |
| If yes, please describe what this will include: | | |

**Biomedical Equipment:**

|  |  |  |
| --- | --- | --- |
| Is the device able to be serviced on site? | Yes | No |
| Is there a dedicated NZ service agent for the product/range? | Yes | No |
| Do you supply Biomedical training? | Yes | No |
| Are service manuals and technical specifications provided? | Yes | No |
| TESTED for essential safety and performance parameters in accordance with AS/NZS3551 (Certificates may be requested) | Yes | No |
| Service can be performed by in-house biomed staff | Yes | No |