**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 [ ]  |