**New Product Listing Application Form**

**National Epidermolysis Bullosa Dressing Scheme (NEBDS)**

**Company Details**

|  |
| --- |
| **Company Name:** Click here to enter text. |
| **ABN:** Click here to enter text. |
| **Address:** Click here to enter text. |
| **Suburb:** Click here to enter text. **State:** Click here to enter text. **Postcode** Click here to enter text. |
| **Postal Address (if different to above):** Click here to enter text. |
| **Suburb:** Click here to enter text. **State:** Click here to enter text. **Postcode:** Click here to enter text. |
| **Contact Name:** Click here to enter text. | **Phone:** Click here to enter text. |
| **Mobile:** Click here to enter text. | **Email:** Click here to enter text. |

**Product Details**

|  |
| --- |
| **Product Name:** Click here to enter text. |
| **Is this product TGA listed?**  | Choose an item. |
| **If yes, what is the ARTG number?**  | Click here to enter text. |
| **In which country is this product manufactured?** | Click here to enter text. |
| **Product Description (please include main components of the product):** Click here to enter text. |
| Click here to enter text. |
| Click here to enter text. |
| **Size (dimensions / volume):** | Click here to enter text. |
| **Indications for use:** Click here to enter text. |
| **How do you recommend the product be used? (ie as a primary or secondary dressing; and / or in conjunction with other products?)** Click here to enter text. |
| Click here to enter text. |
| **If used as a primary or secondary dressing, what other products do you recommend be used with this product?** Click here to enter text. |
| **Are there specific storage requirements for this product?** Click here to enter text. |
| Click here to enter text. |
| **Clinical Evidence:** |
| **Has this product been used in EB patients before?** | Choose an item. |
| **If yes, which subtype of EB has the product been used in?**  |
| Click here to enter text. |
| **If the product has not been used with EB patients before, why do you think it would be useful in EB patients?**  |
| Click here to enter text. |
| **Which product currently on the dressing scheme is your product most similar to? (Comparator)**  |
| Click here to enter text. |
| **Please indicate if comparator is a primary or secondary dressing** | Choose an item. |
| **Why do you think this product should be listed?** Click here to enter text. |
| Click here to enter text. |
| **Please provide the clinical data in support of the product’s effectiveness in EB** |
| **How extensively has this product been trialled in EB?**  |
| Click here to enter text. |
| **Were the trials done locally or internationally?** | Choose an item. |
| **Has this information been subject to peer review? (Eg journal article, conference presentation)** | Choose an item. |
| **If the dressing has not been trialled in EB patients, what evidence is available for the dressing’s efficacy in wound healing? Please provide this evidence.**  |
| Click here to enter text. |
| **Has this information been subjected to peer review?** | Choose an item. |
| **Can you provide the evidence in a form that addresses meaningful outcomes for EB patients?**Meaningful outcomes in EB patients:• Reduced pain• Reduced or resolved malodour• Reduced exudate• Easy to apply and remove dressing or wound product• Dressing stays in place• Dressing does not cause more blistering/skin damage• Dressing is comfortable |
| Click here to enter text. |
| **How often, on average, are dressings required to be changed?**If clinical evidence is available to support this number/interval please provide |
| Click here to enter text. |
| **If available please provide the above information in terms of relevant EB patient outcomes** (eg dressings are required to be changed XX times a week to address malodour, increased exudate) |
| Click here to enter text. |
| **How often are dressings of the comparator required to be changed?** If clinical evidence is available to support this number/interval please provide. If possible please provide this information to address the same EB relevant outcomes as above. |
| Click here to enter text. |
| Click here to enter text. |
| **Please include with this application:** |  |
| **TGA Certificate (where applicable)** |  |
| **A product and pack image for visual representation** |  |
| **Product information or instruction information on use** |  |
| **All relevant Clinical Evidence** |  |
| **Financial Information.** Please note all details provided below will be considered commercial-in-confidence |
| **How much does a single dressing cost?** | Click here to enter text. |
| **How many dressings in a box?** | Click here to enter text. |
| **How much is a box of dressings?** | Click here to enter text. |
| **Is there a discount for bulk ordering?** | Click here to enter text. |
| **If the dressing is to be used as a secondary dressing please indicate the cost of a total dressing change** | Click here to enter text. |