Health practitioner's Acknowledgement and Pledge Form

Printed on the importer's official paper

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Medical Device/Supply | | | | |
| Qty | Intended Use | Model | Medical Device Name | NO |
|  |  |  |  | 1 |
|  |  |  |  | 2 |
|  |  |  |  | 3 |
| Justifications: | | | مبررات الطلب: | |
|  | | | Provide the diagnosis, treatment or prevention for which the device is required | 1 |
|  | | | Provide the reasons why this unregistered device was chosen over a registered device within the KSA or conventional therapies for this particular patient | 2 |
|  | | | Identify and list the risks and benefits associated with the use of the device and indicate how the benefits obtained would outweigh the risks | 3 |
|  | | | Compare the risks of the unregistered device within the KSA with conventional therapies | 4 |
| Declaration: | | |  | |
| I declare with the following:   1. I am fully aware of the health-related risks and benefits of the requested medical device in comparison to conventional therapies or alternative devices available on the market. 2. I have knowledgeable about the available safety and performance information in respect of the requested device. 3. I will report to the SFDA’s National Centre for Medical Device Reporting (NCMDR), any relevant adverse event of which it becomes aware, that involves the medical device (s). 4. Not to reuse the device on a patient other than the one for whom the device were imported, and re-export or destroy it immediately upon completion of its use, providing the SFDA a proof. If this cannot be applied, a justification acceptable to the SFDA shall be submitted. 5. I will cooperate with the SFDA, manufacturer, authorized representative, importer and/or distributer on post market surveillance activities. 6. I have explained or I will explain the following to the patient and/or the patient's family:    * That the Saudi Food & Drug Authority (SFDA) can give no guarantee as to the safety, effectiveness, or quality of the above device and that device is not registered for use in the KSA but that use of the device may be authorized under special provisions.    * The possible risks and benefits of the above device(s). | | | | |
| Patient’s ID: | | | | |
| Healthcare Professional’s Name: | | | | |
| Healthcare Professional’s Organization : | | | | |
| Healthcare Professional’s Signature: | | | | |
| Date: | | | | |