[Company Logo]

Product A DHF

Regulatory Strategy

|  |  |  |
| --- | --- | --- |
| **Rev #** | **Effective Date** | **Description of Change** |
| 00 |  |  |

|  |  |  |
| --- | --- | --- |
| Quality : |  |  |
| [Name], Quality Manager | Date |
| Operations: |  |  |
| [Name], Operations Manager | Date |

Company Name

Address

1. **Purpose & Scope**

The purpose of this document is to define the regulatory strategy for the release of the Product A.

Markets of interest are US, EU, Canada and Japan.

1. **Roles and Responsibilities**

* **Project Management** will be responsible for managing the product deliverables (e.g. design verification, labeling, etc.) required to meet regulatory compliance.
* **Quality** will be responsible for updating this plan/strategy and ensuring that activities are completed according to plan.

1. **Product Description**
   1. **Device Description**

The description of Product A

* 1. **Intended Use**

The intended use

* 1. **Indications for Use**

The indication for use

* 1. **Contraindications**
* Contraindication 1
* Contraindication 2
* Contraindication 3
* etc
  1. **Proposed Marketing Points**

The proposed points that could be useful for marketing purposes, from the Customer Needs Document are as follows:

* Item 1
  1. **Similar Marketed Products and Countries of Use**

|  |  |
| --- | --- |
| **Product** | **Countries** |
|  |  |
|  |  |

1. **Strategy**

The target market countries, along with the regulatory requirements are as follows:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Country** | **Registration/Approval Requirement** | **Clearance Timeline** |
| 1. | USA |  |  |
| 2. | EU (MDR) |  |  |
| 3. | Japan |  |  |
| 4. | Canada |  |  |

*These timeframes are contingent upon the completion of design controls and manufacturing validation, competent authority requirements and ISO Management System registration.*

* 1. **US Strategy**

Classification, Regulatory Statutes, General Requirements.

* 1. **EU Strategy**

Classification, Regulatory Statutes, General Requirements.

* 1. **Japan Strategy**

Classification, Regulatory Statutes, General Requirements.

* 1. **Canada Strategy**

Classification, Regulatory Statutes, General Requirements.

* 1. **Applicable Standards**

List of international Standards that apply to Product A.