[Company Logo]

Product A DHF

Customer Needs

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

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

Company Name

Address

**SECTION 1: INTENDED USER**

|  |  |
| --- | --- |
| Topic | Description |
| Customer and Market Segments |  |
|  |  |
| Users |  |

#### SECTION 2: CUSTOMER AND USER ENVIRONMENT

|  |  |
| --- | --- |
| Topic | Description |
| Environment of Use |  |
| Exclusions |  |

**SECTION 3: CUSTOMER NEEDS [CUSTOMER / INTERNAL REQUIREMENTS]**

| ID # | Need Category | Proposed Need Statement | Priority  (H, M, L) |
| --- | --- | --- | --- |
| CN- | Cost |  |  |
| CN- | Cost |  |  |
|  | | | |
| CN- | User Training |  |  |
| CN- | User Training |  |  |
|  | | | |
| CN- | Patient Impact |  |  |
| CN- | Patient Impact |  |  |
|  | | | |
| CN- | Product Accessibility |  |  |
| CN- | Product Accessibility |  |  |
|  | | | |
| CN- | Product Usage |  |  |
| CN- | Product Usage |  |  |
|  | | | |
| CN- | Product Versatility |  |  |
| CN- | Product Versatility |  |  |
|  | | | |
| CN- | Performance Characteristics |  |  |
| CN- | Performance Characteristics |  |  |
|  | | | |
| CN- | Product Detectability |  |  |
| CN- | Product Detectability |  |  |
|  | | | |
| CN- | Strategic Requirements |  |  |
| CN- | Strategic Requirements |  |  |
|  | | | |
| CN- | Regulatory Requirements |  |  |
| CN- | Regulatory Requirements |  |  |
|  | | | |
| CN- | Env. & Safety Requirements |  |  |
| CN- | Env. & Safety Requirements |  |  |
|  | | | |
| CN- | Other Requirements |  |  |
| CN- | Other Requirements |  |  |