Company Name – Project Name

Product Requirements Document

Document Number

Rev 0 DRAFT

Instructions and Notation

1. The name fields above will be automatically filled in where used in the header and other text.
2. Throughout this template, text in italics on a grey background is guidance, instructions, examples and discussion for the author. This text should be removed when the template is customized for a specific project.
3. The text in blue font has been provided as guidance in thinking through the appropriate requirements for your product. This text should be removed once your requirements have been documented.
4. <Yellow-background> sections, paragraphs, and words need to be made project-specific. These may be **removed,** **customized or replaced** with project-specific information.
5. The text in this template may be edited and tailored to a specific project, even where not highlighted in yellow. Care should be taken to ensure that any edits do not compromise compliance with your design control processes.

**Remove these instructions** when the template is customized for your specific project



The Market Leader in Mechatronics and Detailed Engineering Design Services

Revision History

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| **Revision** | **Date** | **Author** | **Description** |
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# Purpose

This document establishes the Product Requirements for **Product Name** device as part of the *Project Name* Project as defined in *Project Name* Project Development Plan.

The requirements defined in this document are inputs to the detailed design process and form the basis of verification testing.

# Intended Use/Product Description

***Template Instructions:*** *Provide a brief description of the product being developed and its intended use. Note that if this information is contained elsewhere (e.g., Product Development Plan, Risk Management Plan,* ***User Requirements****, etc.,) you just need to include the reference to the document.*

The intended use and product description of the **Product Name** device is described in detail in the *Project Name* User Requirements Specification.

# References

## Applicable Standards

1. IEC 60601-1 2005+A1:2012, Medical Electrical Equipment-Part 1. General Requirements for Basic Safety and Essential Performance.
2. 2nd reference

## Process Documents

1. [doc #] *Project Name* Design Controls
2. [doc #] *Project Name* Risk Management
3. 5th reference

## Project Documents

1. [doc #] *Project Name* Project Development Plan
2. [doc #] *Project Name* User Requirements Specification
3. 8th reference

# Acronyms & Definitions

| **Term** | **Definition** |
| --- | --- |
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|  |  |

# System Requirements

***Template Instructions:*** *Add or remove sections as appropriate for the specific project. Each requirement must have its own unique identifier (Req. ID). Requirements need to be able to be verified and/or validated. Use “shall” terminology to ensure that requirements are not ambiguous.*

*An example is provided here for one method of unique requirement identification: yyy-PRD-nnn,*

*Where:*

*yyy is a 2 or 3 letter designation for the product*

*PRD is designation for Product Requirement*

*nnn is the unique numerical value for the system*

All product requirements are numbered as yyy-PRD-nnnn where yyy is a 2 or 3 letter designation for the *Product Name* device and nnnn is a unique 3 or 4-digit number with leading zeros as needed.

An additional tag may be included in the requirement numbering scheme to indicate that a requirement is a defined risk control. This information would be useful when importing into a requirements management tool or manually generating traceability. Ex: yyy-PRD-nnnn-RC.

The product requirements for *Product Name* are broken into the following categories:

* Physical Characteristics
* Functional & Performance Requirements
* Interfaces
* User Interfaces
* External interface
* Environmental Conditions
* Packaging and Shipping
* Reliability
* Maintenance and Service
* Manufacturing and Test
* Safety, Regulatory, and Standards
* Labeling

## Physical Characteristics

What are the physical attributes and characteristics needed based upon user preference or how it will be used?

* Consider size and weight limitations, color, material compatibility, any other physical requirements of the product.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-101 |  |  |
|  |  |  |

## Functional Requirements

What features and functions must the product have or do to serve the needs of user?

* Consider power, connectivity, and other operational capabilities of the product and processing of inputs and the resultant outputs.
	+ Any special power requirements?
	+ Battery/low power?
	+ Battery life requirements?
	+ Battery charging?
	+ What is the list of motors, heaters, actuators, and sensors that must be electrically controlled?
	+ What are the I/O interface? USB, serial, Ethernet, Wi-Fi, Bluetooth, I2C, SPI, etc.?
	+ What logical states does it go through?
	+ What triggers transition between states?
	+ How is/are the operation(s) started and stopped?
	+ What actions are needed upon completion?
	+ Sensor interfaces?
	+ Actuator interfaces?
	+ Signal processing requirements?
	+ Control algorithm requirements?
	+ What data logging is required?
		- How is this configured?
		- How is it started/stopped?
		- Where is the data stored?
		- How are logs managed? (bounded space? bounded timeframe?)

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-201 |  |  |
|  |  |  |

## Performance Requirements

How well do the product functions need to perform their tasks?

* Consider speed, accuracy, noise, force limits, flow rate or other characteristics your product must have to perform successfully or effectively.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-301 |  |  |
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## Interfaces

### External Interfaces

What else does the product need to interface with and what is required for that to be successful?

* Consider product, peripherals, accessories, consumables, different HW or SW versions, ports, connectors, power, etc.
	+ I/O with external system?
	+ Does the product interact with a host PC, mobile device or networked computer?
	+ Other SW? (databases, network, etc.)
	+ Other devices? (vision systems, motor controllers, sensors, data acquisition systems, etc.)
	+ What operating system(s)?
* Is a SW installer required?

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-401 |  |  |
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### User Interfaces

How does the user need to interact with the product, and how does the design support safe and effective use of the product?

* Consider physical aspects, as well as languages, character sets, auditory, tactile displays, visual, etc.
* What is on the user interface?
	+ Controls?
	+ Status information?
	+ What messages & data displays are needed?
	+ Access controls/permissions?

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-451 |  |  |
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## Environmental Conditions

In what environmental conditions will the product be used or stored?

* Consider temperature, humidity, exposure to liquids, altitude, salt spray, chemicals, electromagnetic fields, vibration, shock, impact, etc.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-501 |  |  |
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## Reliability

How long does the product need to perform its intended function adequately and safely?

* Consider probability of success, duration (time, cycles, etc.), environment, required maintenance, Mean Time Between Failures (MTBF) or Mean Time to Failure (MTTF)
* Consider both system and sub-system components

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-601 |  |  |
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## Maintenance and Service

Will the product require maintenance or service?

* Consider what parts need maintenance or service, frequency, accessibility, tools, level of skill, location, etc.
* Consider the costs of service calls vs. cost of reliability testing

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-701 |  |  |
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## Manufacturing and Test

Will the product perform any manufacturing functions or tests?

* Special production line mode required?
	+ Is manufacturing support SW package needed?
	+ Acceptance testing?
	+ Factory calibrations?
		- How/when will they be performed?
		- Where should the data be stored? (embedded FW, SW)
	+ Additional capabilities of that mode?
* Special engineering mode required?
	+ Additional capabilities of that mode?

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-801 |  |  |
|  |  |  |

## Packaging and Shipping

How does the product need to be shipped?

* Consider contents of shipping package, sterility requirements, shipping standards (e.g., ISTA, ASTM D4169, etc.) that need to be met to protect the integrity of the product and packaging, whether it will be by ground or shipped by air, single, consolidated, or palletized shipments, environmental conditions (temperature, vibration, drop, etc.).
* Consider whether the product contains any dangerous goods (e.g., Lithium batteries, magnets, hazardous chemicals, etc.) as defined by transportation agencies such as the International Air Transport Association (IATA) or US Department of Transportation (DOT). Shipment of dangerous goods may impact your packaging design, method of shipment, required testing and certification, and labeling.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-901 |  |  |
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## Safety, Regulatory Requirements and Standards

What are the potential safety and environmental hazards, and how will the design mitigate these? What regulations and standards is the product required to comply with?

· Consider the type of product (medical, electrical, etc.) and where it will be sold, domestic or foreign, including any local state requirements. Determine what regulations (FDA, EPA, OSHA, REACH, etc.) you are required to comply with and what directives (Medical Device Directive, RoHS, WEEE, etc.) or standards (IEC 60601-1, IEC 62304, ISO 10993-1, etc.) you choose to comply with.

* Consider what mitigations are required to address any safety or environmental hazards defined during your risk analysis activities. This is a key (and required) input for the product requirements document for medical devices.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
| --- | --- | --- |
| yyy-PRD-1001 |  |  |
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## Labeling

What product labels and user documentation are needed?

· Consider the information that needs to be conveyed, including regulatory and standard requirements for labeling, warnings, certifications (CE Marking, UL, etc.), number of product labels, placement, and durability.

· Consider information the user needs to properly install, operate, maintain/service the device - Instructions for Use (User Manual), Service Manual, Installation Guide, training materials, etc.

· Consider whether any of your labeling will be in electronic format or contained in the device software.

| **Req. ID** | **Sub-Category** | **Requirement Description** |
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| yyy-PRD-1101 |  |  |
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