

Product Requirements Document (PRD) (Product Name)

APPROVALS:

Title	Print	Signature	Date

Revision History:

Revision	Summary of Change	Originator
X0	New document	Name

1. Product Description

1.1 Summary

1.2 Intended Use

1.3 Theory of Operation

2. Design Input

1.1 Marketing input

1.2 Sales input

1.3 Customer needs and requests (can be from market surveys, focus groups, questionnaires)

1.4 Customer complaint files for existing relevant products

1.5 Competitive product comparisons (requirements inferred from competitive products)

1.6 Company Medical Device Reports

1.7 Competitive Medical Device Reports

3. Reference Standards

4. Functional Requirements

- 3.1 *Physical Characteristics*
- 3.2 *Material Requirements*
- 3.3 *Electrical Requirements*
- 3.4 *Abilities*
- 3.5 *Limitations*
- 3.6 *Equipment or materials required to use the product*
- 3.7 *Equipment interface requirements*
- 3.8 *Handling and storage requirements*
- 3.9 *Cleaning and Sterilization*
- 3.10 *Re-use*
- 3.11 *Disposal*
- 3.12 *Product maintenance and serviceability*

5. Environmental Conditions

- 4.1 *Temperature*
 - 4.1.1 *Operating:*
 - 4.1.2 *Storage:*
- 4.2 *Humidity*
 - 4.2.1 *Operating:*
 - 4.2.2 *Storage:*
- 4.3 *Shipping, transportation vibration*
- 4.4 *Pressure and Altitude*

4.5 *Electromagnetic Interference*

4.6 *Electrostatic Discharge*

4.7 *Impact Resistance*

6. Performance Requirements

5.1 *Operating parameters*

5.2 *Repeatability and reproducibility*

5.3 *Reliability*

5.4 *Shelf life and Stability*

7. Safety

6.1 *Biocompatibility*

6.2 *Potential or anticipated misuses*

6.3 *Requirements to reduce user induced failure*

6.4 *Mechanical safety features*

6.5 *Electrical safety features*

8. Human Factors

7.1 *User interface*

7.2 *Ergonomics*

7.3 *Training or skills required*

9. Manufacturing

8.1 *Key processes and controls*

8.2 *Lot size and quantity per month*

- 8.3 *Cost*
- 8.4 *Environmental requirements for production*
- 8.5 *Raw materials and suppliers*
- 8.6 *Test methods, standards*

9. Packaging

- 9.1 *Packaging configurations*
- 9.2 *Packaging materials*
- 9.3 *Special shipment requirements*

10. Labeling

- 10.1 *Detail intended use, warning, directions for use, cleaning, expiration date*
- 10.2 *Identify target audience for labeling*
- 10.3 *Language requirements*

11. Regulatory

- 11.1 *Clinical trials*
- 11.2 *Submission type*
- 11.3 *CE mark*
- 11.4 *US and international standards*
- 11.5 *Patent issues*
- 11.6 *Existing technology to avoid*