1.0 Introduction

Product Resources has established, documented, and implemented a Quality system which conforms to the requirements of ISO 9001:2008, ISO 80079-34:2011, and ISO 13485:2003. The Quality system is documented in the Quality Manual. Additional procedures and forms and other documents complement the Quality Manual and are referenced from the Quality Manual or by other documentation such as manufacturing routings.

2.0 Registration

Product Resources' Quality system is examined and certified by an independent, external, accredited registrar or notified body for standards compliance. For ISO 9001 and ISO 13485, this registrar is TUV SUD America. For ISO 80079-34, the notified body is TRaC Global. Registration certificates are displayed in multiple places in the facility, on the company web site, and are made available for distribution to those doing business with Product Resources. A TUV ISO 9001 and/or 13485 mark may be found in marketing materials or in company communications but shall never be found on product. ISO 9001 and 13485 are systems certifications and not product certifications. Note that ISO 80079-34 does not produce a certificate, instead a successful audit by the notified body is proof of compliance. External body audit reports are on file/maintained by QA.

3.0 Quality System Requirements

Product Resources maintains compliance to the requirements of these Quality management standards and takes an integrated approach to conformance within a single system:

ISO 9001:2008
Quality Management Systems – Requirements
This standard provides the core of our Quality system requirements. All other (below) standards augment the requirements of ISO 9001 for particular regulated markets.

ISO 80079-34:2011 (formerly EN 13980)
Explosive Atmospheres – Part 34: Application of Quality Systems for Equipment Manufacture
This standard is complementary to ISO 9001, requires ISO 9001 certification as a prerequisite, and is applicable to products intended for use in potentially explosive atmospheres. It is required by the ATEX Directive (of the EU) and for the IECEx certification scheme.

ISO 13485:2003
Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
This standard can be both stand-alone and complementary to ISO 9001 – complementary in our application – and is applicable to medical device products. It is the preferred method of proving conformity of the QMS to the Medical Device Directive (of the EU), and is a QMS standard accepted by the medical device industry.

4.0 Scope and Exclusions

The scope of this Quality system covers the operations of Product Resources LLC, whose facilities are located at 4 Mulliken Way, Newburyport, Massachusetts, USA. The facility is approximately 33,000 square feet of manufacturing and test space, office space, and storage space, with room for expansion.

For each Quality standard to which Product Resources complies, there are standard-specific scopes (these match the certificates issued where applicable) and exclusions.

<u>For ISO 9001:</u>

Scope: Design, Development, Manufacture and Service of Custom Instrumentation, Devices, Controls, and Integrated Systems Using Embedded Systems, Electronic, Precision Mechanical, Optical, and Pneumatic Technologies

Exclusions: Installation is excluded for compliance to this standard.

<u>For ISO 80079-34:</u>

Scope: Product Resources manufactures and services custom instrumentation, robotics, controls, and integrated systems using embedded systems, electronic, precision mechanical, optical, pneumatic,

and fluid technologies for devices used in potentially explosive atmospheres.

Exclusions: Design, development, and installation are excluded for compliance to this standard. For this standard, Product Resources is acting as a contract manufacturer and is not directly putting product into the market.

For ISO 13485:

Scope: Manufacture and Service of Custom Instrumentation, Robotics, Controls, and Integrated Systems Using Embedded Systems, Electronic, Precision Mechanical, Optical, Pneumatic and Fluid Technologies for application in the Medical Device Industry

Exclusions: Design, development, and installation are excluded for compliance to this standard because Product Resources is acting as a contract manufacturer and is not directly putting product into the market. Product Resources does not manufacture or service implantable devices and therefore the special requirements for implantable devices do not apply and are excluded. Product Resources does not manufacture or service sterile medical devices and therefore the special requirements for sterile medical devices do not apply and are excluded.

5.0 Responsibility

The Chief Quality Officer (CQO) has the responsibility and authority to maintain the Quality system compliant to ISO 9001:2008, ISO 80079-34:2011, and ISO 13485:2003 and to continually improve its effectiveness. Using internal Quality audits, Quality Assurance is able to verify the implementation of the procedures described in the Quality Manual. The Internal Audit procedure (90-2000-8.2.2) describes the internal auditing program.

6.0 Documentation Tiers

Product Resources' documented Quality system is in three tiers, two of them authored by Product Resources:

- Tier Zero is the level of the standard, for instance the ISO 9001:2008, ISO 13485:2003, or ISO 80079-34:2011 standards. These standards are available from Quality Assurance and are available from Document Control. Requirements stem from these documents, and these

documents provide industry-standard requirements models for Quality systems. These are international standards and are not authored by Product Resources.

- Tier One is Product Resources' Quality Manual. It contains procedures describing the implementation of Quality systems at Product Resources.

- Tier Two is comprised of additional procedures, forms, and other documents that will be discussed below.

7.0 Quality Manual (Tier One)

The Quality Manual is the Tier One documentation that the employees of and those doing business with the company should refer to in order to understand Product Resources' Quality system. The manual itself has no document number but is a collection of all documents with 90-2000-X numbers, where 90 is Product Resources' category for Quality system documents, 2000 was chosen because this version of the manual was fully re-written for compliance to the 2000 version of ISO 9001 (which represented a significant departure from earlier versions) and structurally preserved for the 2008 version of ISO 9001, and X typically relates to one or more sections of the ISO 9001:2008, ISO 80079-34:2011, and ISO 13485:2003 standards. The typical use of the standard section(s) for X makes it easier to go back and forth between Product Resources' Quality Manual documents and the external standards.

The Quality Manual has controlled distribution (see the distribution procedure 90-2000-4.2.2). Only copies available from Document Control including binders in distribution and Quality Manual procedures posted on the company website (considered to be in distribution themselves) are to be considered current and valid. Copies printed from Document Control or from the website are only to be considered current at the time of printing; a user of the document later than this in time must verify that the given revision still matches the current revision as evidenced either by looking at the document and its current revision again in Document Control or the website.

Changes to the Quality Manual shall be made in accordance with the Control of Documents procedure 90-2000-4.2.3.

In the Quality Manual procedures, Product Resources will address the overall ISO 9001:2008, ISO 80079-34:2011, and ISO 13485:2003

requirements and will describe the Product Resources processes that fulfill them.

8.0 Additional Procedures, Forms, and Other Documents (Tier Two)

Additional procedures, forms, and other documents complement the Quality Manual and are the Tier Two documents. Here are examples:

Procedures referenced by the Quality Manual that provide additional, more-detailed instructions for carrying out tasks – details beyond the scope of the Quality Manual.

Forms for a variety of purposes to provide documented evidence of the Quality system. Manufacturing routings and any other types of documentation may reference forms to use.

Manufacturing drawings, schematics, work instructions, test procedures, etc. that describe how to process a product or the product's design. These are pointed to by manufacturing routings or referenced by other manufacturing documents.

9.0 Sequence and Interaction of Quality Manual Procedures

The document 90-2000-INT graphically describes the sequence and interaction of the QMS processes. Descriptions of sequence and interaction are also found in the text of Quality Manual procedures as the processes are described.

Resolving Documentation Conflicts: Though every effort is always made to prevent conflicting information, the following standards of precedence will be used to resolve conflicts if these arise: If there is a conflict between the textual description of a process and the graphical depiction, the textual description will take precedence. Also, the document directly describing any given process will take precedence over any other document describing the process as a matter of reference. For example, the Control of Documents procedure 90-2000-4.2.3 will take precedence for all matters of document control over, for example, the design control procedures 90-2000-7.3.X, which may cite document control as a matter of reference. At the same time, employees shall make QA aware of any such conflicts discovered so that they may be corrected.

10.0 Outsourcing Policy

It shall be noted in this first Quality Manual procedure as policy that when Product Resources chooses to outsource any process that affects product conformity to requirements, it remains Product Resources' responsibility to ensure that the process is in control, and Product Resources remains ultimately responsible for the product. See the Purchasing procedures 90-2000-7.4.1 and 90-2000-7.4.2, the Supplier Guidelines Manual 43-2248, and the purchased material verification procedure 90-2000-7.4.3 for details about the control of outsourced product.