WRITTEN BY:	DATE:	APPROVED BY:	DATE:
J. Caruso	Digitally signed by John M. Caruso DN: cn=John M. Caruso gn=John M. Caruso c=United States l=US o=Product Resources ou=Quality Assurance e=jcaruso@prodres.com Reason: I am the author of this document Location: Date: 2013-03-17 17:33-04:00	C. Libelo	Digitally signed by Carolyn Libelo DN: cn=Carolyn Libelo gn=Carolyn Libelo c=United States l=US o=Product Resources ou=Product Resources e=clibelo@prodres.com Reason: I am approving this document Location: Date: 2013-03-18 14:24-04:00

1.0 Purpose

The purpose of this Quality Manual procedure is to describe the role of the Management Representative, particularly in relationship to Product Resources' Quality system and interfacing with regulatory bodies and customers for matters of Quality and regulatory compliance.

2.0 Policy, Responsibility, and Procedure

The responsibility and authority for establishment, implementation, and maintenance of Product Resources' Quality system is delegated to the Management Representative. Product Resources' Management Representative shall be the Quality Assurance Manager.

The Management Representative shall speak for the company on all matters of Quality and shall be responsible to see that the Quality system is maintained to current ISO 9001 standards and other standards as identified in 90-2000-4.1, including ISO 80079-34 and ISO 13485. The Management Representative shall report to management on the system's status and need for any improvement. The Management Review is the vehicle for this reporting and initiation of change.

The Management Representative shall be Product Resources' primary contact for matters of regulatory compliance. The Management Representative shall field inquiries from customers regarding regulatory compliance and shall advise customers on the same. He or she shall also meet with auditors from regulatory bodies maintaining product listings for products that Product Resources manufactures. This includes initial factory audits, product surveillance audits, and Quality system audits for product certifications that have accompanying Quality system requirements, such as product controlled under the ATEX and Medical Device Directives, which require ISO 80079-34 and 13485 compliance, respectively. The Management Representative in this role maintains product regulatory reports; this activity is described in 90-2000-4.2.3, Control of Documents.

The Management Representative is responsible for the effective coordination of activities related to product controlled under the ATEX Directive, which is product used in potentially explosive atmospheres (intrinsically safe product). The specifics of these activities are described throughout this Quality Manual in all instances in which special treatment is required for such product above and beyond Product Resources' base Quality system.

The Management Representative is also responsible for the effective coordination of activities related to product controlled under the Medical Device Directive; medical devices are controlled under this Directive. The specifics of these activities are described throughout this Quality Manual in all instances in which special treatment is required for such product above and beyond Product Resources' base Quality system.

Ensuring the awareness of the Quality system and customer and regulatory requirements shall also be the responsibility of the Management Representative. This will be accomplished in the following manner, and the Management Representative is ultimately responsible for these items:

- Postings will be made of internally-generated and/or externally (customer)-generated charts and reports. The annual Management Review and other review meetings held periodically (such as the quarterly Supplier Review Board meetings and monthly internal audit meetings) are normally the source of the charts and reports.

- There will be sharing of feedback from customers and regulatory bodies with Product Resources personnel.

- There shall be awareness training developed and delivered for the ATEX Directive and the Medical Device Directive including information about these Directives and also, and most importantly, what Product Resources employees must pay attention to and do to ensure that Product Resources fulfills all requirements. (See also 90-2000-6.2.2, Competence, Awareness, and Training.) This training highlights special provisions in Product Resources' Quality system made to satisfy the requirements of the ATEX and Medical Device Directives and their importance.