ISO 13485

A Higher Standard Matters

in Medical Device Quality Management

INTERSTATE BATTERIES®

Outrageously Dependable®

Dave Corbett

Medical Battery Product Manager

Why is Interstate ISO 13485 certified?

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

CERTIFICATE

No. QS1 17 12 96551 004

Certificate Holder: Interstate All Battery
4301 121st Street
Urbandale IA 50323
USA

Certification Mark:

Scope of Certificate: Design and Development, Manufacture, and Distribution of Batteries for Hearing Aids, Infusion Pumps, Patient Monitors, Mobile Carts, and X-Ray Machines

Standard(s): ISO 13485:2003

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned abo
has established and is maintaining a quality management system that meets the requireme
the listed standards.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M7010

Effective Date: 2017-12-20
Expiry Date: 2018-12-31

Manuel Bradaric
MHS Certification Manager

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TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

TÜV SÜD EN ISO 13485

- Interstate Batteries is registered by the FDA, the only regulatory requirement for manufacturers with facilities in the United States
- ISO 13485 certification was essential to market batteries for Infusion Pumps, Patient Monitors and Hearing Aids in Canada
- Canada has a higher bar…

The impact of ISO-driven Quality Management was immediate – and continues today.

ISO VS FDA:
Do you want assurance before there's a problem – or after?

The FDA does not test or inspect products prior to product release or monitor facilities or manufacturing processes.

The FDA can inspect facilities at any time. If records and procedures are not in compliance, they can cease production, seize product and levy fines.

ISO 13485 certified Quality Management Systems under MDSAP are given a "pass" on surveillance inspections.

Our ISO certificate shows compliance BEFORE a product problem is found.

Compliance to FDA regulations is more of an "Honor System" and reacts to problems.

ISO 13485:2016

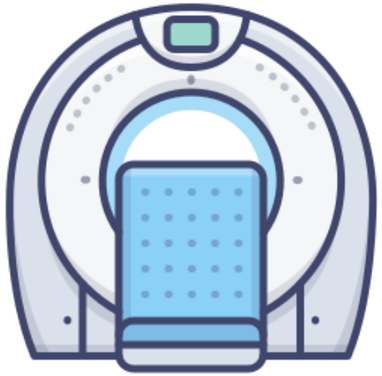
FDA

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

ISO 9001 vs. ISO 13485: the difference matters

One is to ensure customer satisfaction for all types of businesses,

FROM CONSTRUCTION TO RETAILERS, FLORIST SHOPS AND CLEANERS



The other is an increasingly stringent set of standards for applying sound risk management processes

SPECIFICALLY FOR MEDICAL DEVICES TO ENSURE PATIENT SAFETY

ISO 13485 adds 5 critical areas to ISO 9001

Product specifics

Regulatory requirements

Customer satisfaction

Documentation requirements

Continual improvement

Product Specifics

Every aspect of product development is managed through a Risk Management process

OEM battery specifications are analyzed and reproduced

- Matching of cells and components
- Identifying opportunities for improvement

Manufacturing processes are validated and monitored

- Welding, soldering, gluing & assembly processes are analyzed
- Weld and solder processes are confirmed with pull testing
- Assembly personnel are trained under a mentorship

Any changes to these processes or equipment must be reviewed and new Risk Analysis must be performed.

New product must be validated in the field under actual use conditions.

Documentation requirements

The FDA GMP regulations only mentions Risk Management once

FDA

"Design validation shall include software validation and risk analysis, where appropriate."

ISO 13485:2016

"The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained."

ISO 13485 MENTIONS RISK MANAGEMENT OVER 30 TIMES

WITH A SPECIFIC REQUIREMENT TO DOCUMENT ALL RISK MANAGEMENT ACTIVITIES

Customer satisfaction

ISO 13485 requires analysis of customer needs beyond matching the specifications of an OEM battery.

ISO MEANS YOU AND YOUR PEERS HAVE A SAY IN PRODUCT DESIGN AND PERFORMANCE

This can include design refinements, packaging or labeling improvements.

The MED0016 package was changed from individually boxed to a 5-pack

— Biomed techs

Customer satisfaction

With ISO 13485, we must take ACTION when receiving complaints

Sec. 820.198 Complaint files

Manufacturers must maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit.

8.2.2 Complaint handling

The organization shall document procedures for timely complaint handling and also determine the need to

initiate corrections or corrective actions

Customer satisfaction: ISO 13485 gives you a voice in reducing risk

A level above FDA requirements

The ISO 13485 standard provides streamlined processes to collect, analyze and act upon this information and then check on the effectiveness of the response.

CAPA – Corrective Action / Preventative Action

- **Corrective Actions** are responses to non-conforming product identified by customers or production data.
- **Preventative Actions** are opportunities for improvements identified by customer feedback or by our staff.

Continual improvement

“Good today” is never enough

Quality data from production and customer experience

ISO 13485 helps provide structure for Interstate to continually improve our products.

The FDA has no such requirement.

How does ISO certification benefit you?

ISO 13485 = more accountability = reduced costs and risk

Reduced risk

Safeguard patients, hospital staff and equipment

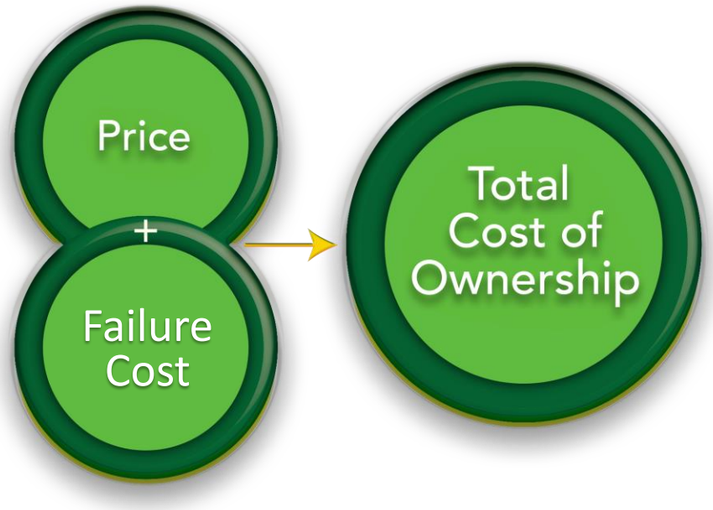
- Increased Risk Management focus above FDA Reduced liability exposure

Reduced cost of ownership

- Less labor lost to re-installing failed batteries
- Less administrative $$ > fewer returns/warranty credits

Greater supplier accountability

- Immediate response to product quality concerns
- Reporting leads to product/process improvements



INTERSTATE ALL BATTERY CENTER

Tested and Trusted like no other brand

Interstate's 7-Point Quality Assurance:
the industry's most rigorous, ongoing testing process

1 Highest Manufacturing Standards
Including IEC, ISO 13485, FDA

Zero Tolerance Enforcement

Interstate Distribution + Testing Center

2 Comprehensive Inspection
Examine for shipping damages, proper labeling & condition

3 Conformance Test
Ensure terminals are correct & conform to dimensional standards

4 Spec Check
Verify dimensional specs

5 Life Cycle Testing
Measure battery discharges through all cycles until wear-out

6 Voltage Validation
Validate voltage across all stages of charge

7 Weight Verification
Evaluate weight against OEM specifications

When lives are counting on it, ISO 13485 certification means quality you can count on

50% of hospital service calls are battery related*.

Make sure your supplier's products have credentials you can count on.

**According to AAMI "All Charged Up - The many challenges to battery maintenance" - Martha Vovkley 3/2014*