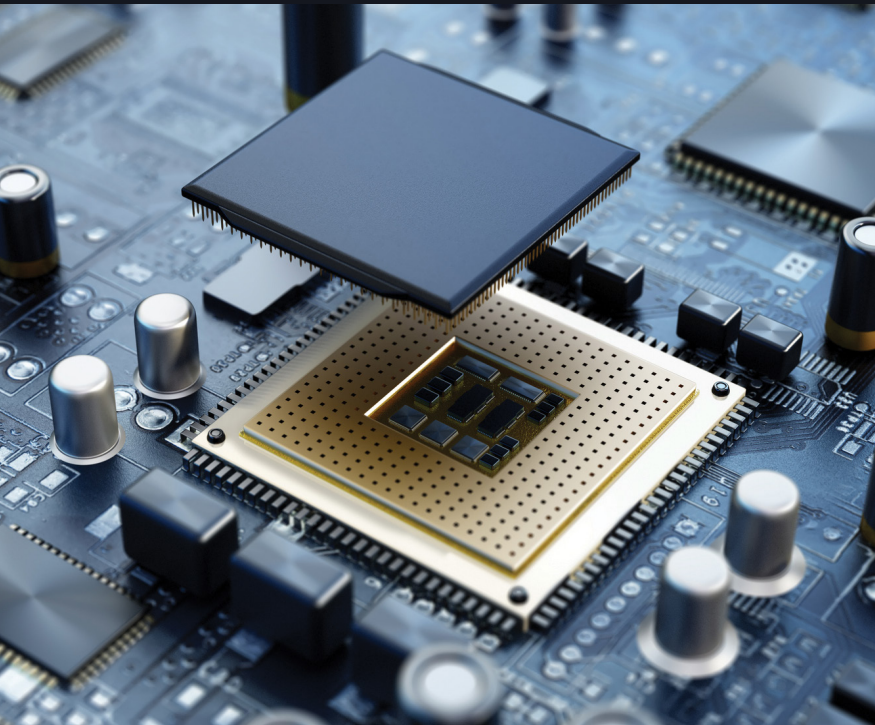




OEM/ODMS' INDUSTRIAL AND MEDICAL COMPUTER CERTIFICATION HANDBOOK

Welcome to Teguar's Industrial and Medical Computer Certification Handbook! At Teguar, we understand the critical importance of certifications in the industrial and medical sectors. Our commitment to quality and compliance ensures that our computers meet the stringent requirements of these industries, providing reliable and safe solutions for OEM/ODM partners.

In this downloadable guide, we've compiled a comprehensive list of certifications that OEM/ODM companies may need to cover when working with industrial and medical computers. Whether you're navigating regulatory standards or industry-specific requirements, this guide will help you understand the certifications necessary to ensure your product's success.

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ISO 13485



The medical device manufacturing sector, especially as it pertains to computers and tablets, presents a unique set of challenges and opportunities. As an engineer in this industry, understanding the landscape of the regulations and quality assurance is paramount. One of the key standards you will come across is ISO 13485. But what exactly is it, and why is it so important?

What is ISO 13485?

ISO 13485 is an internationally recognized standard that outlines the requirements for a Quality Management System (QMS) in the medical device industry. It is designed to support organizations in demonstrating their ability to produce medical devices that meet both customer expectations and regulatory requirements.

Why is ISO 13485 important?

Regulatory Compliance

Compliance with ISO 13485 is often a prerequisite for accessing and operating in various global markets. A robust QMS complying with ISO 13485 can expedite the approval processes and smooth the path to market.

Risk Management

The standard places a strong emphasis on risk management throughout the product lifecycle, aiming to minimize risks related to safety and performance.

Customer Trust

Holding an ISO 13485 certification enhances the credibility of your products, making it a competitive differentiator in the market.

Key Components You Should Know

Documentation

The standard mandates comprehensive documentation for quality processes, risk assessments, and other facets of the QMS.

Traceability

Particularly relevant to engineers is the requirement for traceability in design, manufacturing, and distribution stages, ensuring accountability at each step.

Internal Audits

Regular internal audits are a must, and you, as an engineer, might find yourself involved in these to ensure compliance.

Practical Tips for Engineers

Get Acquainted with the Terminology

Familiarize yourself with the jargon and definitions unique to ISO 13485. This will enable you to understand how your role fits within the QMS.

Align Design Practices

Ensure that your design practices are in sync with ISO 13485 requirements, particularly when it comes to risk management and documentation.

Collaborate Across Departments

You'll need to work closely with quality assurance, regulatory affairs, and even marketing teams to ensure that the product meets the set guidelines.

Bottom Line

Understanding ISO 13485 doesn't have to be an overwhelming task. By taking the time to familiarize yourself with its key components and its importance in the medical computer industry, you can position yourself and your organization for success.

By keeping these aspects in mind, not only will you uphold the highest quality standards, but you will also contribute to your organization's long-term success in a highly competitive and regulated industry.

IEC 60601-1



Stepping into the realm of medical-grade computers and tablets comes with its own set of regulations and standards. Among the most critical is IEC 60601-1, which acts as a guiding framework for the safety and effectiveness of medical electrical systems. This guide aims to simplify the standard and outline what new engineers in the field need to know.

What is IEC 60601-1?

IEC 60601-1 is an international standard that specifies the general requirements for the safety and essential performance of medical electrical equipment and systems. This standard is vital for ensuring that such equipment meets the necessary safety benchmarks and performs reliably under various conditions.

Why is IEC 60601-1 Important?

Market Access

Compliance with IEC 60601-1 is often required for market entry. Failure to adhere can result in the denial of product approval.

Risk Management

Understanding and implementing the risk management aspects of IEC 60601-1 can significantly minimize hazards associated with medical electrical equipment.

Reputation

Non-compliance can lead to recalls or other adverse events, tarnishing both the product and company reputation.

Key Components You Should Know

Safety Objectives

The standard includes critical objectives concerning electrical, mechanical, and radiation safety.

Risk Analysis

Engineers are expected to conduct rigorous risk assessments that meet the standard's guidelines, often using techniques like FMEA (Failure Mode and Effects Analysis).

Performance Criteria

IEC 60601-1 also mandates that equipment must meet certain performance characteristics to be considered safe and effective.

Practical Tips for Engineers

Safety-First Design

Engineers should approach the design phase with safety as the top priority, ensuring all aspects of the device comply with IEC 60601-1.

Continual Learning

New amendments and updates to the standard occur frequently. Make it a practice to stay updated.

Cross-Functional Collaboration

Work closely with the regulatory and quality assurance departments to ensure that your designs are compliant.

Bottom Line

Understanding IEC 60601-1 is not just about ticking off a compliance box; it's about ensuring the safety and efficacy of medical-grade computers and tablets. As you start your journey in this specialized field, use this standard as a roadmap to guide your engineering practices.

EN-60601-1



If you're an engineer stepping into the specialized realm of medical-grade computers and tablets, knowing the ropes of EN 60601-1 is essential. Recognized in European nations, this standard sets the criteria for medical electrical devices' safety and performance. This blog post breaks down what you need to know about EN 60601-1 to navigate this complex landscape successfully.

What is EN 60601-1?

EN 60601-1 is a European standard that sets out the general requirements for safety and essential performance of medical electrical equipment. Adapted from the international standard IEC 60601-1, it incorporates additional clauses and specifications to align with European regulations.

Why is EN 60601-1 So Crucial?

Access to European Markets

Compliance is mandatory for entering or operating within the European Union, making it a cornerstone in your product's market strategy.

Legal Safety Net

Meeting the EN 60601-1 standard also provides some level of legal protection in the event of a liability claim related to product safety.

Quality Assurance

The standard assures stakeholders that your product meets the highest safety and performance measures, enhancing your brand's reputation.

Distinguishing EN 60601-1 from IEC 60601-1

Adaptations for Local Legislation

EN 60601-1 often includes amendments to adhere to specific European laws and guidelines, providing an extra layer of compliance.

Regulatory Framework

This standard is harmonized under the EU's Medical Device Regulations (MDR), making it essential for CE marking.

Key Components for Engineers

Safety Goals

Like its IEC counterpart, EN 60601-1 emphasizes electrical safety, mechanical safety, and radiation safety.

Documentation

Detailed documentation, including risk assessments and performance tests, is mandatory for compliance and must be incorporated into the design process.

Software Requirements

Given that medical-grade computers and tablets are software-driven, compliance with software-related safety and performance measures is a must.

Practical Tips for Engineers

European Focus

Always keep the European market's specific needs and conditions in mind during the design and testing phases.

Collaboration

Engage with your company's regulatory affairs team early and often to ensure you're aligned with the EN 60601-1 standards from the outset.

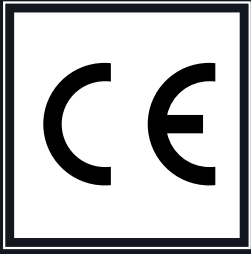
Continuing Education

The regulatory landscape is constantly evolving. Keep up-to-date with the latest amendments to EN 60601-1.

Bottom Line

Navigating the requirements of EN 60601-1 can be challenging, but it's a necessary hurdle for any engineer in the field of medical-grade computers and tablets. With this guide, you're now better equipped to understand and implement the standards that will set you on the path to success in the European market.

CE MARK



When it comes to medical-grade computers and tablets designed for the European market, the CE Mark is your passport for entry. But what does it signify, and what do you, as an engineer in this field, need to know about it? This information will guide you through the what, why, and how of CE Marking.

What is CE Marking?

The CE Mark is a certification mark that indicates a product has met the European Union's health, safety, and environmental protection requirements. For medical-grade computers and tablets, CE Marking is often mandatory, serving as an endorsement of quality and safety.

Why is CE Marking Important?

Regulatory Compliance

CE Marking is a legal requirement for medical devices sold within the European Economic Area (EEA).

Market Trust

A CE Mark boosts consumer confidence, as it signals that the product has met rigorous European standards.

Cross-Border Sales

Products with the CE Mark are free to move throughout the entire EEA, widening your potential market.

Navigating the Path to CE Marking

Identifying Relevant Directives

For medical-grade computers and tablets, the most relevant directives are usually the Medical Device Regulations (MDR) and sometimes the EMC and RoHS Directives.

Technical Documentation

Prepare a technical file that includes detailed information about the product design, risk assessment, and testing methods.

Notified Bodies

Consult with a Notified Body, if necessary, to validate your technical documentation and compliance with the relevant directives.

Key Considerations for Engineers

Material Selection

Ensure that the materials used are compliant with RoHS directives if applicable.

Software Verification

If the computer or tablet involves complex software, ensure it meets the software-specific requirements under the MDR.

Post-Market Surveillance

Engineers should also be prepared for ongoing compliance requirements, including post-market surveillance and reporting.

Practical Tips for Engineers

Cross-Team Collaboration

Work closely with your quality and regulatory teams to ensure that the technical file is both complete and compliant.

Gap Analysis

Perform a gap analysis to identify any areas where your product might not yet meet the necessary requirements.

Continuous Learning

Regulations are often updated, so it's crucial to stay informed about changes that could affect your product's compliance.

Bottom Line

CE Marking is more than just a regulatory hurdle; it's a badge of quality and safety that can set your medical-grade computers and tablets apart in a crowded marketplace. By understanding its significance and the steps needed to achieve it, you can set both yourself and your products up for success in the European market.

IP RATINGS



From design stages to the finished product, IP ratings offer engineers a definitive guide to ensure their devices are fit for medical environments. This blog post aims to illuminate what IP Ratings mean and why they are essential for engineers in the field.

What Are IP Ratings?

Ingress Protection (IP) Ratings provide a standardized measurement of how well a device resists intrusion from dust, water, and other particles. Generally expressed as “IP” followed by two numbers (e.g., IP65), the first digit represents resistance to solid particles, while the second signifies resistance to liquids.

Why Do IP Ratings Matter?

Infection Control

Medical settings demand stringent hygiene measures. Devices with higher IP Ratings can be more easily sanitized, aiding infection control.

Reliability

Understanding IP Ratings can help engineers build more durable products that are suited to the medical environment.

Compliance and Marketability

In some cases, an IP Rating may be a requirement for market entry or part of a product specification sought by potential buyers.

IP Ratings: Decoded for Engineers

First Digit: Solid Particle Protection

A ‘6’ means the device is dust-tight, crucial in sterile medical settings.

Second Digit: Liquid Ingress Protection

A ‘5’ signifies protection against water jets from any direction, and a ‘7’ indicates the device can be submerged in water up to 1m.

Essential Considerations for Engineers

Material Selection

Choose materials that can withstand the rigors of a medical setting while still achieving the desired IP Rating.

Sealing Techniques

The quality of seals, like O-rings and gaskets, can significantly affect the IP Rating.

Testing

In-house testing or third-party certification is essential to validate the IP Rating claimed.

Practical Tips for Engineers

Benchmarking

Check out existing medical-grade computers and tablets to see what IP Ratings they offer and aim to meet or exceed these standards.

Teamwork

Work closely with your design and quality assurance teams to address all the aspects that could impact your device’s IP Rating.

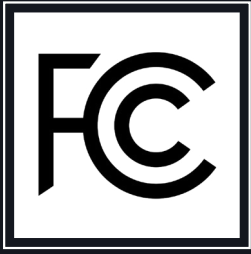
Lifecycle Testing

Regularly review the IP Rating during the product’s lifecycle, as wear and tear can affect the device’s performance over time.

Bottom Line

Understanding IP Ratings is not just a box to tick in the design process; it’s a pivotal aspect that can significantly impact a medical device’s performance, reliability, and marketability. As an engineer entering this sector, gaining a strong grasp of IP Ratings is a critical step in your career development.

FCC PART 15



FCC Part 15 might not be the most glamorous part of your journey as an engineer in the field of medical-grade computers and tablets, but it is undoubtedly one of the most important. This standard lays down the rules for the electromagnetic interference of devices.

What is FCC Part 15?

FCC Part 15 is a regulation set by the Federal Communications Commission (FCC) that governs the electromagnetic interference of electronic devices, including medical-grade computers and tablets.

Why is FCC Part 15 Important?

Compliance

Adhering to FCC Part 15 is a legal requirement for the sale and distribution of electronic devices in the United States.

Device Reliability

Compliance ensures that your devices won't interfere with other electronic products, and likewise, will operate effectively despite external interference.

Marketability

A product that is FCC compliant can be marketed as such, providing an additional layer of trust for prospective buyers.

Key Concepts of FCC Part 15 for Engineers

Intentional vs. Unintentional Radiators

Medical-grade computers and tablets often incorporate Wi-Fi, Bluetooth, and other radios, making them intentional radiators. Compliance is essential for both types of radiators.

Certification Process

Most medical-grade devices require a certification process, which involves detailed testing by an accredited lab.

Labeling Requirements

FCC-compliant products usually require specific labeling to indicate compliance, which needs to be considered in the design stage.

Practical Steps for Engineers

Pre-Compliance Testing

Conduct early in-house EMC (Electromagnetic Compatibility) testing to gauge your device's likelihood of passing the FCC's tests.

Partner with Experts

Collaborate with EMC consultants or testing labs to better understand how your device can meet FCC Part 15 requirements.

Documentation

Maintain meticulous records of your design and testing processes. These may be needed to prove compliance or to troubleshoot any issues that arise during certification.

Bottom Line

FCC Part 15 may seem like a hurdle, but in reality, it's a foundational aspect of device design and marketing in the United States. By understanding and adhering to these regulations, engineers can ensure not only legal compliance but also create medical-grade computers and tablets that stand out for their reliability and performance.



Understanding UL/cUL certifications is a rite of passage for engineers developing medical-grade computers and tablets. These certifications serve as a hallmark of safety and reliability, especially in the North American market. On this page, we will break down the essentials of UL/cUL certifications and why they matter.

What is UL/cUL Certification?

Underwriters Laboratories (UL) and its Canadian counterpart (cUL) provide third-party certification that signifies a product meets specific safety standards. For medical-grade devices, these certifications are often indispensable.

Why UL/cUL Matters

Regulatory Compliance

Having a UL/cUL certification is a prerequisite for selling medical-grade computers and tablets in certain markets, including the United States and Canada.

Customer Trust

These certifications instill confidence among users and buyers, offering third-party verification of your product's safety features.

Legal Protection

Certifications also serve as a liability shield in case of mishaps, as they demonstrate due diligence on part of the manufacturer.

Key Concepts for Engineers

Types of UL/cUL Certifications

Different types of certifications might apply, depending on the device's specific function and risk factors.

Testing Phases

Expect multiple phases of product testing, ranging from the initial design to the final product, to secure a UL/cUL certification.

Ongoing Compliance

UL/cUL certification is not a one-time event; regular inspections and compliance checks are required to maintain the certification.

Practical Steps for Engineers

Initial Risk Assessment

Begin by conducting a risk assessment to identify potential safety hazards that your device could pose.

Engage Early

Engage with UL/cUL experts and testing facilities early in the product development process to ensure smooth certification later on.

Keep Detailed Records

Maintain comprehensive documentation, as you'll need to provide this during the testing and certification process.

Bottom Line

UL/cUL certifications may seem daunting, but they're a crucial part of developing safe, reliable, and marketable medical-grade computers and tablets. As an engineer, mastering the intricacies of these certifications can give you an invaluable skill set that sets you—and your products—up for success.

FDA 21 CFR PART 820



Navigating the complex world of regulations is a critical task for any engineer in the medical device industry. Among the most important of these regulations is FDA 21 CFR Part 820, otherwise known as Quality System Regulation (QSR). This page aims to guide engineers through the critical points of this regulation and why it's important for medical-grade computers and tablets.

What is FDA 21 CFR Part 820?

FDA 21 CFR Part 820 lays out the Quality System Regulation (QSR) requirements that medical device manufacturers must follow. The regulation ensures that devices are consistently produced in a manner that meets applicable requirements and specifications.

Why Is It Important?

Regulatory Compliance

Adherence to FDA 21 CFR Part 820 is required for the marketing and sale of medical-grade computers and tablets in the United States.

Patient Safety

Ensuring that devices meet this rigorous quality system helps guarantee their safety and effectiveness in patient care.

Company Reputation

Compliance with QSR reflects the quality and reliability of your products, impacting your brand's reputation in the market.

Key Sections Engineers Should Focus On

Design Controls

The requirements for planning, inputs, outputs, reviews, verification, validation, and changes in design are outlined under this section.

Production and Process Controls

This covers everything from equipment validation to process validation, providing guidelines for producing consistent products.

Record-keeping and Documentation

Understanding the documentation requirements is crucial, as failure to maintain adequate records can result in compliance issues.

Practical Steps for Engineers

Risk Management

Incorporate risk management into all stages of the development cycle, as required by the regulation.

Collaboration

Work closely with the quality assurance team to ensure that all aspects of the QSR are integrated into the product development process.

Internal Audits

Conduct regular internal audits to evaluate the effectiveness of the Quality Management System (QMS) and to prepare for external inspections.

Bottom Line

Understanding FDA 21 CFR Part 820 is more than a compliance checklist; it's a foundational element for engineers in ensuring the quality and safety of medical-grade computers and tablets. Whether you are new to the field or looking to deepen your expertise, a thorough grasp of this regulation is essential for career growth and success in the development of medical-grade devices.

REACH



REACH regulation might not be the first thing on your mind as an engineer in the medical-grade computer and tablet field, but it's a crucial aspect if you aim to tap into the European market. This post walks you through what REACH is and why it's a cornerstone in the design and production of medical-grade devices.

What is REACH?

REACH is a European Union regulation that governs the production and use of chemical substances, ensuring a higher level of protection for human health and the environment. Medical-grade computers and tablets often involve chemicals in components like plastics, circuits, and batteries, making REACH compliance essential.

Why REACH Matters

Access to European Market

Non-compliance with REACH means that you won't be able to distribute or sell your products in EU countries.

Environmental Responsibility

REACH encourages the use of safer substances and promotes environmental sustainability.

Consumer Trust

Being REACH-compliant can be a selling point, reinforcing your product's safety and ecological credentials.

Key Areas of Focus for Engineers

Substance Inventory

You'll need to identify all substances in your device and check whether they are on the SVHC (Substances of Very High Concern) list.

Supplier Collaboration

Work closely with suppliers to ensure that all components are REACH-compliant.

Documentation

Maintaining proper records of compliance activities is vital for proving adherence to REACH guidelines.

Practical Tips for Engineers

Early Engagement

Integrate REACH considerations at the early stages of the design process to avoid costly modifications later.

Use Compliant Materials

Opt for materials and components that are already confirmed as REACH-compliant to simplify the compliance journey.

Continuous Monitoring

Keep an eye on updates to REACH regulations and SVHC lists, as changes could impact your product's compliance status.

Bottom Line

REACH compliance is not optional but a necessity for engineers working on medical-grade computers and tablets intended for the European market. A keen understanding of REACH regulations not only helps in product development but also instills a culture of sustainability and consumer safety in the engineering process.

ROHS



RoHS may be just an acronym on a spec sheet, but for engineers in the medical-grade computing field, it represents a world of crucial considerations. This page unpacks what RoHS means and why it's a cornerstone for your work in developing medical-grade computers and tablets.

What is RoHS?

RoHS stands for the Restriction of Hazardous Substances. It's a European regulation aimed at limiting the use of specific hazardous materials found in electrical and electronic equipment (EEE), including medical-grade devices.

Why RoHS is Important

Market Entry

Compliance is mandatory for products being sold in the European Economic Area (EEA) and many other jurisdictions that have adopted similar regulations.

Eco-Friendly Products

RoHS promotes the creation of eco-friendly devices by restricting hazardous substances, aligning with sustainability goals.

Consumer Confidence

RoHS compliance indicates a product's safety and environmental impact, thereby building consumer trust.

Key Considerations for Engineers

Restricted Materials

Engineers must be aware of the specific materials that are restricted under RoHS, such as lead, mercury, and cadmium.

Component Sourcing

Collaborate with suppliers to ensure that components used are RoHS-compliant.

Testing and Verification

Products must be tested and verified for compliance, which may require partnerships with specialized labs.

Practical Tips for Engineers

Design Phase

Integrate RoHS considerations as early as the design phase to avoid costly adjustments down the line.

Documentation

Maintain meticulous records of compliance, as you may need to furnish these to authorities or customers.

Stay Updated

RoHS regulations are continually updated. Keep an eye out for any changes that might affect your products.

Bottom Line

RoHS isn't just a checkbox; it's an integral part of designing and manufacturing sustainable and safe medical-grade computers and tablets. Understanding RoHS compliance can position you, as an engineer, in a proactive stance, ensuring that your designs are both innovative and compliant.

ISO 9001



For engineers in the industrial computing world, quality isn't just a buzzword—it's a necessity. ISO 9001 serves as a globally recognized quality management standard that can significantly influence the design, development, and manufacturing of industrial computers and tablets. This page explores the core elements of ISO 9001 and why it is important for engineers to understand them.

What is ISO 9001?

ISO 9001 is a standard set forth by the International Organization for Standardization, outlining criteria for a quality management system (QMS). The standard focuses on customer satisfaction, management efficiency, and continual improvement.

Why ISO 9001 Matters

Customer Expectations

Adhering to ISO 9001 helps meet and exceed customer expectations for product quality and reliability.

Competitive Advantage

ISO 9001 certification is often viewed as a benchmark of quality, offering a competitive edge in the marketplace.

Process Improvement

The standard promotes an organization-wide culture of continual improvement, directly affecting product quality and efficiency.

Key Concepts Engineers Should Know

Process-Oriented Approach

ISO 9001 encourages a focus on processes and their interactions, which is vital for developing complex systems like industrial computers and tablets.

Documentation

Proper documentation of processes and quality standards is essential, both for compliance and for internal reference.

Risk-Based Thinking

Engineers should be aware of how to assess and manage risks throughout the product development process.

Practical Steps for Engineers

Early Integration

Incorporate ISO 9001 guidelines early in the design phase to facilitate a smoother path to compliance.

Collaborate with QMS Team

Regularly coordinate with the team responsible for the Quality Management System to ensure alignment on ISO 9001 standards.

Auditing and Monitoring

Be prepared for both internal and external audits by maintaining up-to-date documentation and metrics.

Bottom Line

ISO 9001 isn't merely a certification to hang on a wall. It is a comprehensive approach to quality that should permeate every aspect of an engineer's role in developing industrial computers and tablets. By understanding and applying the principles of ISO 9001, engineers can contribute to building high-quality, reliable products that stand up to the demands of industrial applications.

ATEX



When it comes to developing industrial computers and tablets, ensuring safety in hazardous locations is paramount. ATEX certification is a key factor that engineers need to consider for products deployed in potentially explosive atmospheres. This post serves as an essential guide for engineers new to ATEX standards.

What is ATEX?

ATEX stands for “ATmosphères EXplosibles,” a European Union directive that covers equipment and protective systems intended for use in potentially explosive atmospheres. The regulation aims to ensure the safety of both the equipment and the personnel operating it.

Why ATEX is Important for Engineers

Safety Standards

ATEX certification guarantees that your products meet the highest safety standards, reducing the risk of accidents in hazardous areas.

Market Access

For industrial computers and tablets destined for the European Union or countries that recognize ATEX, certification is mandatory.

Legal Compliance

Failure to comply with ATEX standards can result in hefty fines, legal penalties, and a tarnished brand reputation.

Key Concepts Engineers Should Master

Zones and Categories

ATEX identifies different zones (0, 1, 2 for gas; 20, 21, 22 for dust) and categories (1, 2, 3) to indicate the level of protection required. Engineers must understand which zones and categories their products will be used in.

Technical File and Risk Assessment

The ATEX certification process involves creating a detailed technical file that includes a thorough risk assessment of the product.

Essential Health and Safety Requirements (EHSRs)

EHSRs are a set of minimum requirements that products must meet to be ATEX certified. Engineers should be familiar with these standards and how to achieve them.

Tips for Navigating ATEX Certification

Engage Early with Notified Bodies

Early engagement with notified bodies can help clarify ATEX requirements specific to your product.

In-House Testing and Third-Party Verification

While preliminary testing can be done in-house, a third-party assessment is typically required for certification.

Continuous Compliance

ATEX compliance isn't a one-time event; engineers must stay updated on amendments to the directive and ensure ongoing compliance.

Bottom Line

Understanding ATEX is critical for engineers developing industrial computers and tablets for hazardous locations. By familiarizing yourself with the intricacies of ATEX certification, you can contribute to safer and more reliable products, while also ensuring market access and legal compliance.

NEMA



When you're an engineer working on industrial computers and tablets, you quickly learn that not all enclosures are created equal. Understanding NEMA standards can help you design products that meet specific environmental and usage conditions. This page aims to provide engineers with the knowledge they need to navigate NEMA ratings effectively.

What is NEMA?

The National Electrical Manufacturers Association (NEMA) develops standards for the electrical manufacturing industry, one of which includes performance ratings for enclosures used to house electrical components.

Why NEMA Ratings Matter

Reliability and Durability

Industrial computers and tablets with the appropriate NEMA ratings are more reliable in demanding conditions, such as exposure to dirt, water, or corrosive chemicals.

User Safety

NEMA standards also consider the safety of the people who will interact with the equipment, providing guidelines to protect against electric shock and other hazards.

Regulatory Compliance

NEMA ratings can often be a requirement for specific industries or applications, and non-compliance may lead to fines or restrictions.

Key Aspects Engineers Should Understand

NEMA Rating Numbers

The NEMA rating system uses numbers (e.g., NEMA 4X, NEMA 12) to signify the types of environments for which an enclosure is suited. Engineers need to understand what each number represents.

Material Choices

Different materials may be more suitable for achieving certain NEMA ratings, such as stainless steel or polycarbonate enclosures.

Testing Procedures

Understanding the testing methods used to validate a NEMA rating will help engineers design products that meet these standards effectively.

Practical Guidance for Engineers

Consult Early and Often

Consult with the product management and compliance teams early in the design process to identify which NEMA ratings are necessary for your product's intended applications.

Use Trusted Suppliers

When sourcing components, prefer suppliers who have a track record of providing NEMA-compliant products.

Ongoing Verification

Regularly review and, if necessary, retest your products to ensure they continue to meet the required NEMA standards as both your products and the standards evolve.

Bottom Line

NEMA ratings offer more than just a set of guidelines; they are a benchmark for product quality and safety in the industrial computing world. Engineers who understand how to navigate these standards will find themselves better equipped to create robust and reliable products.

MIL-STD-810



When durability and reliability are non-negotiable, MIL-STD-810 becomes a standard of interest—even for engineers in the industrial computing sphere. This post will give you the insights you need to understand what MIL-STD-810 is, why it matters, and how to factor it into your engineering projects.

What is MIL-STD-810?

MIL-STD-810 is a U.S. military standard that describes various environmental tests to simulate conditions that a product may encounter during its lifetime. While originally designed for military applications, it has gained broad adoption in rugged industrial settings.

Why MIL-STD-810 is Essential for Engineers

Ensuring Product Robustness

Complying with MIL-STD-810 is a testament to a product's durability, signifying it can operate effectively under extreme conditions.

Expanding Market Reach

MIL-STD-810 compliance can be a strong selling point, opening up opportunities in sectors like mining, construction, and oil and gas.

Risk Mitigation

Understanding and meeting the standard can help minimize the risk of product failure and its associated costs and brand damage.

Key Elements Engineers Should Focus On

Test Methods and Procedures

MIL-STD-810 includes a variety of test methods, from thermal shocks to vibration resistance. Engineers must identify which tests are relevant for their specific product.

Tailoring to Industrial Needs

The standard allows for "tailoring," meaning tests can be modified to better simulate the device's actual environmental conditions.

Verification and Documentation

Record-keeping is crucial; engineers should document how the tests were tailored, conducted, and the results.

Practical Tips for Engineers

In-House vs. Third-Party Testing

Initial testing can be done in-house, but third-party testing is often necessary for formal certification.

Interdisciplinary Coordination

Consult with other departments like procurement and quality assurance to ensure that components meet MIL-STD-810 requirements.

Lifecycle Considerations

Be aware that compliance may need to be re-evaluated if any changes are made to the product or its components during its lifecycle.

Bottom Line

MIL-STD-810 isn't just a military standard; it's a benchmark for reliability and ruggedness in industrial computers and tablets. By getting to grips with this comprehensive standard, engineers can significantly contribute to the quality and reliability of the industrial devices they develop.

ATE



In today's fast-paced industrial landscape, efficiency and precision are key. Automated Test Equipment (ATE) offers both, helping engineers ensure that their industrial computers and tablets meet rigorous performance criteria. This page aims to equip engineers with the foundational knowledge they need to leverage ATE effectively.

What is ATE?

Automated Test Equipment is a specialized system designed to perform tests on different devices automatically. In the realm of industrial computing, ATE can be used for various tests, including functionality, performance, and long-term reliability.

Why ATE is Important for Engineers

Enhanced Efficiency

Manual testing can be time-consuming and error-prone. ATE streamlines the testing process, saving both time and resources.

Consistent Results

ATE provides a level of consistency that is difficult to achieve with manual testing, making it easier to meet quality standards.

Scalability

As production volumes increase, ATE allows for seamless scaling of testing operations, ensuring that quality remains consistent.

Key Concepts Engineers Should Know

Types of ATE

There are various forms of ATE, including digital, analog, and mixed-signal testers. Engineers should identify which type is most relevant to their specific industrial computing products.

Test Scripting

ATE tests are usually executed based on pre-defined scripts. Engineers should understand how to develop or modify these scripts for their unique test cases.

Maintenance and Calibration

ATE systems require regular maintenance and calibration to provide accurate results. Engineers should be aware of this ongoing commitment.

Practical Guidelines for Engineers

Involve ATE Early

Considering ATE requirements early in the design phase can make it easier to integrate the technology into your testing process later.

Validate Before Automating

Before fully transitioning to ATE, validate its performance against manual tests to ensure that it meets your quality benchmarks.

Monitor and Adapt

Keep an eye on ATE-generated data to catch any potential anomalies and adjust your testing strategies accordingly.

Bottom Line

In the ever-evolving field of industrial computing, Automated Test Equipment offers a robust solution for engineers focused on product quality and efficiency. By understanding the principles and practicalities of ATE, engineers can better prepare for the challenges and opportunities that lie ahead.

CB SCHEME



When designing industrial computers and tablets for a global market, compliance with international safety and performance standards is a must. One such pathway to worldwide acceptance is the CB Scheme. This guide will help engineers understand the importance of the CB Scheme and how to make it work for them.

What is the CB Scheme?

The CB Scheme is an international program for the exchange and acceptance of product safety test results among participating laboratories and certification organizations. Managed by the IECEE, it simplifies the process of gaining multiple national safety certifications.

Why is the CB Scheme Important for Engineers?

Simplified Global Entry

A CB Test Certificate can make it easier to obtain national certifications, streamlining the entry into various global markets.

Cost-Effectiveness

Instead of undergoing multiple tests for different countries, one set of tests can suffice, thereby saving time and financial resources.

Risk Mitigation

A CB Test Certificate serves as a validation of product safety and performance, reducing the potential for non-compliance issues and recalls.

Key Points Engineers Should Understand

Eligibility and Requirements

Not all countries participate in the CB Scheme, and each may have additional local requirements. Engineers need to research this beforehand.

Test Standards

The CB Scheme typically refers to IEC standards for testing, which can vary based on the product category. Engineers should identify the relevant standards for their devices.

Ongoing Compliance

Compliance is not a one-time effort. Engineers must stay updated on any changes to relevant standards and adjust the product accordingly.

Practical Tips for Engineers

Early Planning

Considering CB Scheme requirements early in the product development cycle can save time and resources in the long run.

Collaboration

Work closely with your legal and compliance teams to ensure you meet all the requirements of the CB Scheme and any additional local standards.

Record-keeping

Maintain detailed documentation throughout the design and testing phases, as this will be crucial for the certification process.

Bottom Line

For engineers in the field of industrial computing, understanding the CB Scheme can pave the way for easier international market entry and less regulatory hassle. By familiarizing themselves with this system, engineers can better prepare for the global challenges that lie ahead.

UL-60601-1



UL-60601-1 is a globally recognized safety standard specifically designed for medical electrical equipment. It outlines stringent safety requirements and performance criteria that medical computers and tablets must meet to ensure patient and operator safety.

Why UL-60601-1 Matters for Engineers

Regulatory Compliance

UL-60601-1 certification is often mandatory for medical devices in many countries, including the United States and Canada. Non-compliance can result in market access barriers and legal issues.

Patient Safety

Compliance with UL-60601-1 helps mitigate potential risks associated with medical computing devices, ensuring patient safety and reducing liability for manufacturers.

Quality Assurance

Achieving UL-60601-1 certification enhances the reputation and trustworthiness of your medical computing products, setting them apart from uncertified alternatives.

Key Aspects Engineers Should Know

Certification Levels

UL-60601-1 offers different levels of certification, including basic safety, essential performance, and collateral standards. Engineers must determine the appropriate level based on the device's intended use and features.

Testing Requirements

The certification process involves rigorous testing, including electrical safety, electromagnetic compatibility, and risk analysis. Engineers should be well-versed in these requirements to design products that comply from the outset.

Documentation and Traceability

Maintaining comprehensive documentation of the design process, materials used, and testing methods is critical for UL-60601-1 certification. Proper documentation ensures traceability and simplifies the certification process.

Practical Tips for Engineers

Early Evaluation

Engage with certification experts early in the design phase to assess compliance requirements and integrate them into the product design, reducing the risk of costly redesigns later.

Prototype Testing

Conduct preliminary in-house testing to identify potential issues before submitting the product for formal certification. This can save time and resources.

Continuous Compliance

Remember that certification is an ongoing commitment. Any modifications or updates to the device must be assessed for their impact on compliance with UL-60601-1.

Bottom Line

UL-60601-1 certification is not just a regulatory checkbox; it is a crucial assurance of safety and quality for medical computers and tablets. Engineers well-versed in these certification requirements are better equipped to design products that not only meet but exceed the expectations of the medical industry, ultimately contributing to improved patient care and device reliability.

Teguar is committed to helping OEM/ODM partners navigate the complexities of industrial and medical computer certifications. Our team of experts is ready to assist you in selecting the right products and ensuring compliance with the necessary standards. For inquiries, customization options, or further assistance, please don't hesitate to contact us:

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We look forward to supporting your industrial and medical computer needs and helping you achieve success in your projects.

