

Medical Devices

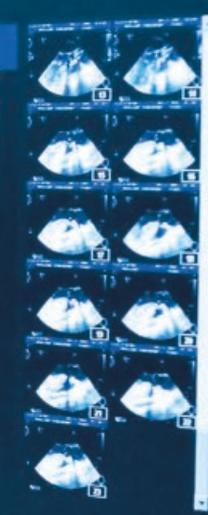
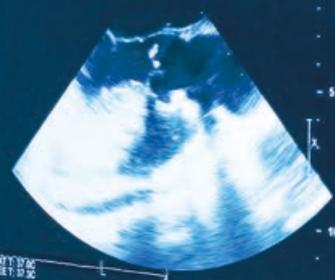
Technical Safety

Protects Your Patients



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Technical safety protects your patients

Experience saves lives

TÜV AUSTRIA has been serving customers domestically since 1872 and is now active internationally in more than 40 countries.

Years of experience and know-how pertaining to state-of-the-art technology, regulations, legislation, and risks make TÜV AUSTRIA a competent partner with the highest degree of acceptance in the business world, by the public, and government agencies. Whether planning, commissioning, advanced development, or testing: TÜV AUSTRIA is your individual partner who will support you right from the start in order to implement medical device applications reliably and securely.

TÜV AUSTRIA Medical Devices. With safety.

TÜV AUSTRIA Medical Devices offers comprehensive services in the following areas:

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- Inspection of medical gas pipe installations	05
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Ongoing technical safety testing of medical devices

oTST or STK

Technical medical devices have become indispensable in health facilities, where complex devices can make the difference between life and death and the wellbeing of patients. Device safety, that is, proper function in accordance with the application, is thus extremely important.

Legislation in the form of medicinal product laws (e.g., the Medical Device Law) mandates health facilities to carry out regular inspections at intervals of 6 to 36 months, depending

on the type of device.

In Austria, safety and the flawless function of technical medical devices must be tested and ascertained in the form of "technical safety inspections" for the protection of patients.

Calibration of medical devices

MTK

The highest precision of devices with a measuring function must be ensured in order to make correct diagnoses. Which is why the Austrian Medical Device Directive requires the calibration of medical devices for accuracy at intervals of 12 to 24 months, depending on the type of device.

- Blood pressure monitors
- Thermometers for determining body temperature
- Foot pedal ergometers
- .

TÜV AUSTRIA offers on-site calibration of medical devices

Trend

Rapid technical development is also apparent in the supply networks of health facilities. The use of increasingly larger and more complex high current systems and gas pipe installations massively impact the need for calibration of medical devices.

Die Zahl der am europäischen Markt befindlichen Medizinprodukte wird zwischen 500.000 und einer Million bei ungefähr 8.000 verschiedenen Arten geschätzt.

Source: AGES



Inspection of high voltage systems in health facilities

A properly installed and maintained high voltage system (including back-up power supplies and emergency lighting systems) is a basic requirement for safe and disruption-free operation of a health facility and also avoids unnecessary costs for the operator.

Ensuring the supply of important, life-saving devices and system components is essential in health facilities in the event of internal malfunctions or a failure in the public network.

TÜV AUSTRIA has decades of experience with health facility power supplies. With the knowledge of our experts, we are happy to support you in planning, installing, and operating high voltage systems and back-up power supply systems for health facilities.

Inspection of medical gas pipe installations

The central supply of individual areas of a health facility with medical gases is extremely important and also very complex. A system error or the failure of components can have a serious impact on the health and even lives of patients.

Which is why the flawless function of medical gas pipe installations is so important.

TÜV AUSTRIA offers ongoing inspections of your systems in accordance with manufacturers' specifications and any applicable regulations.



Hygiene testing for bedpan disinfection

To reduce the spread and transmission of pathogens, bacteria, and germs in healthcare facilities to a minimum, hygiene is of utmost importance in modern healthcare.

In hospitals, rehabilitation centers, outpatient clinics, and nursing homes, countless bedpans (body bowls) are disinfected and prepared for safe reuse. For bedpans, the principle of thermal disinfection is used.

Health authorities require regular examination to ensure proper functioning of the bedpans and thus minimize the risk of unwanted disease transmission.

TÜV AUSTRIA fulfills this requirement by inspecting the function of your bedpans at regular intervals using the most modern equipment to ensure the required disinfection quality.

Thermoelectric measurement of small steam sterilizers

Compartment volumes less than 60 liters

Hygiene-VO 2014, which permits the operation of steam sterilizers in accordance with EN ISO 13060 or ÖN EN 285, is based on Austrian legislation.

Moreover, the Medical Devices Act stipulates that only validated processes for recycling medical devices may be used. In order to prove compliance, operators must take annual thermoelectric measurements on steam sterilizers.

TÜV AUSTRIA can take such measurements for you on-site. We use modern radio data loggers that feature the required three temperature sensors as well as a pressure sensor. You will receive a detailed test report immediately after the measurements have been taken.

Consistency testing of X-ray equipment

As an inspection body in accordance with the Austrian Accreditation Law, TÜV AUSTRIA is an independent and competent partner in the area of consistency testing.

This service is offered for all makes and models of X-ray equipment. In close collaboration with the Institut für Strahlenschutz und Dosimetrie [Institute for Radiation Protection and Dosimetry], we conduct inspections with

our own measuring equipment and phantoms at intervals as specified in ÖNORM S 5241.

As an independent testing laboratory that gains neither from the purchase nor repair or maintenance of X-ray equipment, TÜV AUSTRIA guarantees an objective evaluation of the inspected system.

Technical safety officer

Technical safety officer

The Austrian Hospital and Convalescence Law (KAKuG) governs the responsibilities of the technical safety officer. It mandates that healthcare facilities appoint a technical safety officer (TSO) who is responsible for the technical safety and proper functioning of medical-technical devices and the technical equipment used in the institution for the protection of patients. We offer know-how and provide legal compliance:

TÜV AUSTRIA experts are available to act as the technical

safety officer for your hospital. Our experience resulting from many years of working as technical safety officers in different hospitals, guarantees the necessary sense of judgement in implementing legal and normative requirements.

Safety expert

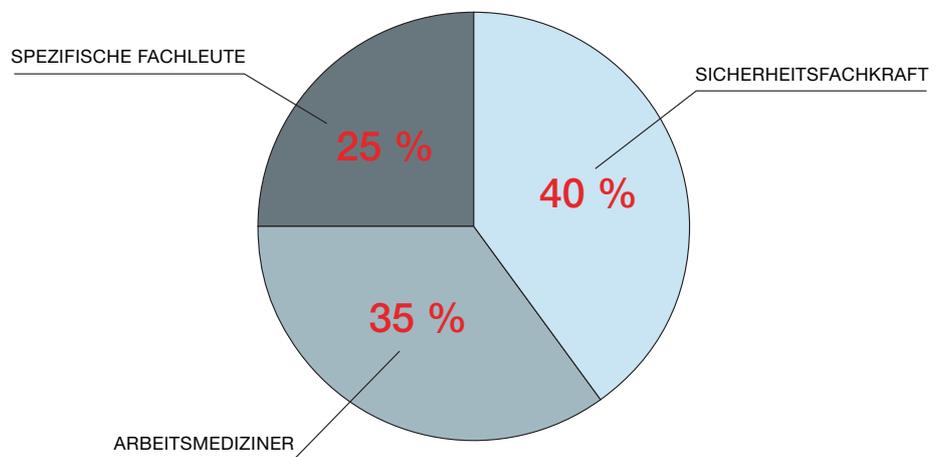
Safety expert

Workers in healthcare facilities are exposed to numerous hazards: transmitted diseases, blood, and hazardous materials can threaten nursing and cleaning personnel and doctors. The purpose of preventative services, namely the use of safety experts, is to advise the employer with the goal of minimizing risks.

Are you lacking time or personnel? – Contact us, our experts will be happy to support you. An objective opinion from an outside perspective also helps to prevent "tunnel vision."

The trained and experienced safety experts at our Safety Technical Center advise a large number of hospitals and rehabilitation centers as well as various rescue and medical services.

Allocation of prevention time according to the Austrian National Regulation for Health and Safety



Facts

To comply with the Austrian National Regulation for Health and Safety, healthcare facilities are obligated to order preventative services. Preventative services entail safety experts (SEs) and preventive medicine (PM). The amount of time required for preventative services depends on the number of employees at the facility.

Source: acc. to § 82a (5) ASchG



Reports and incident investigation

The risk of incidents or close calls in connection with medical devices must be minimized in principal. Should an incident occur, the cause of the incident must be thoroughly investigated.

TÜV AUSTRIA experts are available to determine the cause of an incident or close call and generate the corresponding report.

Software for maintenance and facility management

The importance of powerful software for facility management (FM) and maintenance has increased significantly in recent years for hospitals, outpatient clinics, and other health facilities. In addition to the documentation requirements under the Austrian Medical Devices Law, technical departments are increasingly challenged with regard to

scheduling and cost analysis.

TÜV AUSTRIA has been a system partner of Loy & Hutz AG, the German market leader for healthcare industry FM software for decades, and can also advise you in this important area.



Your benefits

- Benefit from our decades of experience in the medical devices industry and the high level of professional expertise of our employees in the development of regulations and standards.
- We are objective. We have no close ties or dependencies with industry, trade, or government agencies and are, therefore, completely unbiased.
- Based on years of experience in the healthcare industry, we are familiar with all processes and are thus able to perform our work at your location as quickly and disruption-free as possible.
- Save time and money by inspecting multiple device groups and with package offers for all systems requiring inspection (e.g., medical devices/electrical installations/doors and gates/elevators), carried out by a single company. We offer comprehensive services!
- Our internationally recognized inspections and test reports are based on quality-assured checklists. This will allow you to achieve legal compliance while saving time and money.
- The measuring and examination devices we employ are modern, calibrated regularly and constantly updated with the latest equipment.
- Strategically located service centers in Austria save you money when it comes to experts traveling to your location.
- According to the Medical Device Directive, only suitable persons and institutions may perform technical safety inspections.
TÜV AUSTRIA Medical Devices is an accredited inspection body for medical devices with proof of authorization to render services.



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Vienna location

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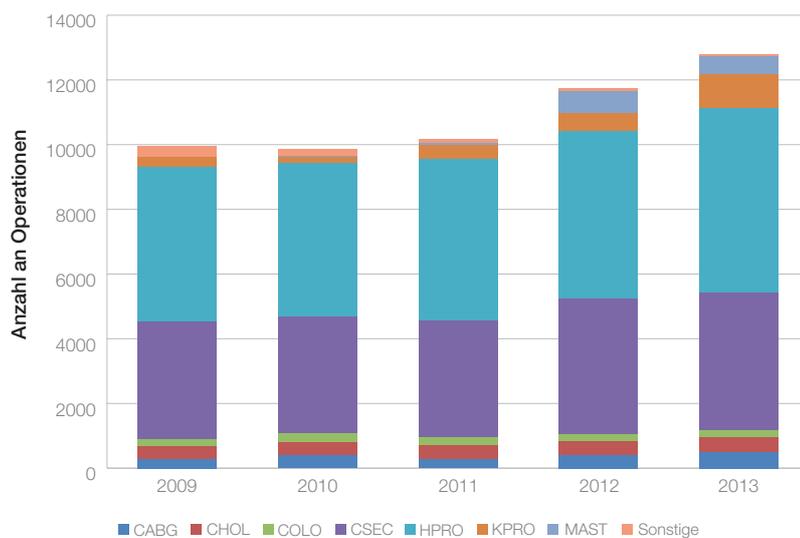
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Nosocomial infections in Austria

Trend

Lack of hygiene in world-wide health facilities leads to so-called nosocomial infections. These infections are of great significance and represent a significant challenge in the care of patients. The term 'healthcare associated infection' is increasingly being used in international specialist literature.



CABG=Koronararterien-Bypass-Operation, CHOL=Gallenblasen-Operation, COLO=Operation am Dickdarm, CSEC=Kaiserschnitt-Operation, HPRO=Hüftprothesen-Operation, KPRO=Knieprothesen-Operation, MAST=Mastektomie

Source: BMGF

Other services from the TÜV AUSTRIA Group

Preventive hygiene concepts

Hygiene as quality assurance feature

Minimize the existing risk of infectious disease through preventive strategies.

Our TÜV AUSTRIA experts will create a customized hygiene concept for your facility. We advise medical practices, nursing and convalescence homes, hospitals as well as special institutions, rehabilitation facilities, institutes, and companies engaging in "workplace health promotion." Your hygiene concept will be developed by highly qualified and experienced hygiene experts based on legal and normative specifications and taking into consideration the guidelines of the Robert Koch Institute and recommendations from professional societies.

In a clear and traceable way, we will inform you of recognized and binding standards for hygiene management and develop on your behalf suitable measures for achieving your goals.

The activities of the listed professional groups are governed in the Hospital and Convalescence Law. Furthermore, the 'Heimverordnung' (Retirement Home Act) stipulates that you as a supporting organization must ensure that at least one person who has completed the special training for hygiene is available at each facility.

Our TÜV AUSTRIA experts provide all legal and normative services in accordance with the latest state of the art and technology in the area of hygiene. The employment of well-trained and experienced hygiene experts is a key element in infection management for health facilities.

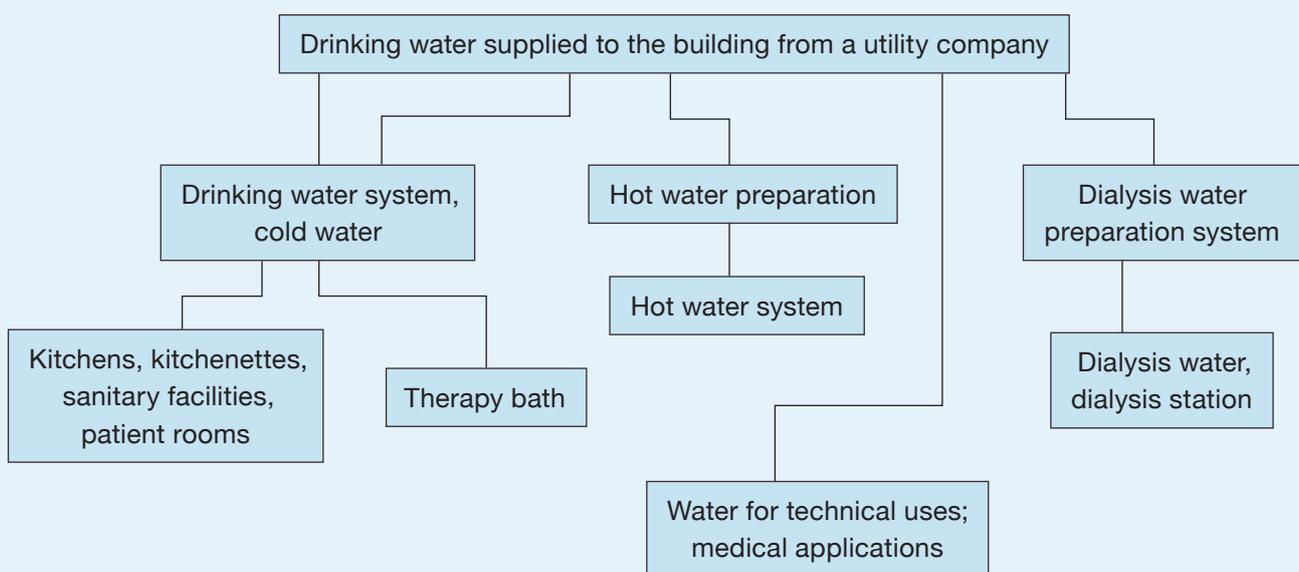
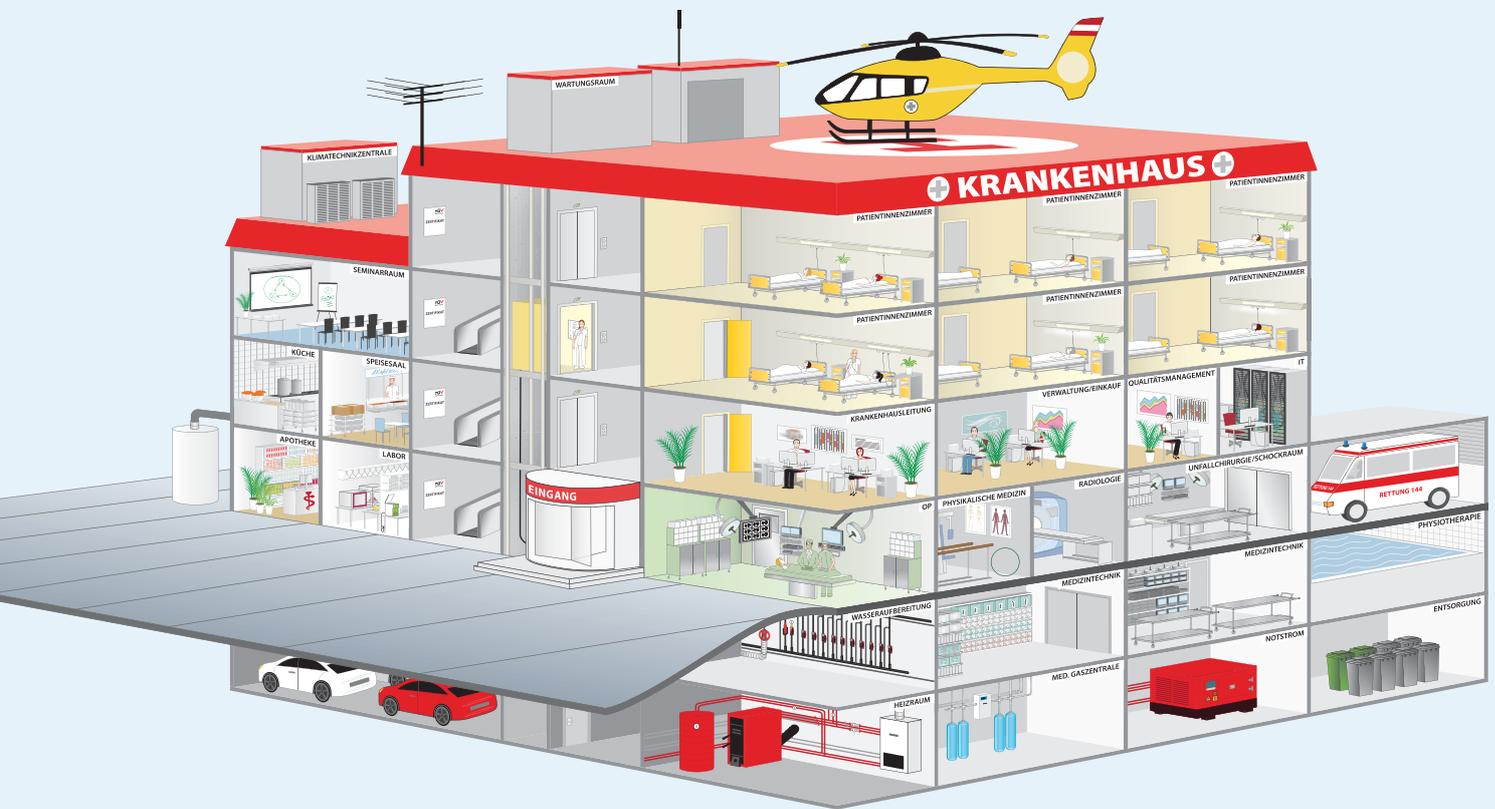
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**Medical Specialist for Hygiene and Microbiology,
Hygiene Officer (HO) and Hygiene Expert (HE)**



Drinking water hygiene

Anyone involved in hygiene in the healthcare industry knows the complexity pertaining to water hygiene. Handling water may seem straight forward, but when it comes to special equipment the issue of hygiene becomes much more complex.

Drinking water is used for many purposes in health facilities: for preparing hot water, therapy baths, producing dialysis water, and supplying technical systems, such as steam humidifiers, or for treatment units in medical practices.

Our TÜV AUSTRIA experts are very involved in water hygiene, taking special account of microbiological contamination. Many years of experience have resulted in the development of a recognized quality assurance system.

We support you in minimizing health, economic, and legal risks by implementing and recording a few simple measures.

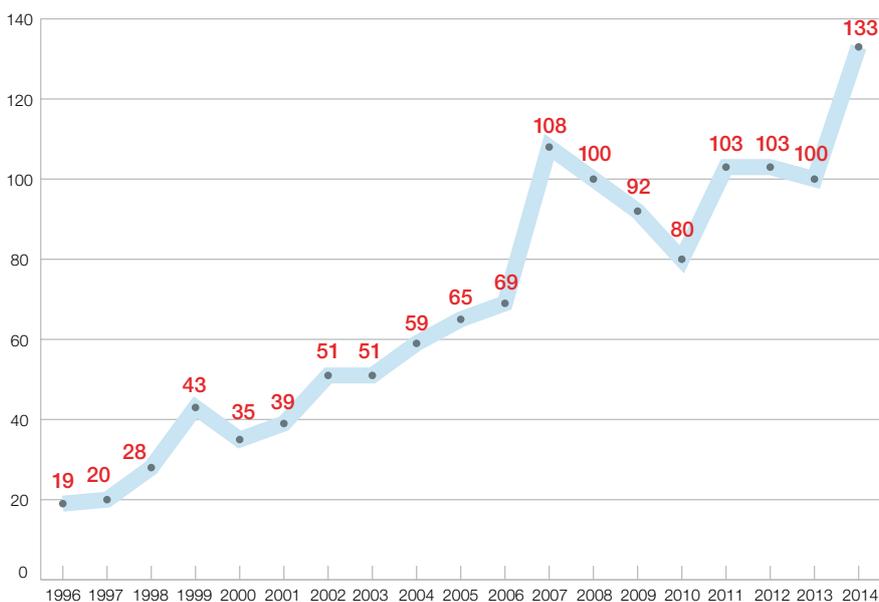
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Incidence of Legionnaire's disease in Austria, 1996 – 2014



n = 1298

Source: AGES

Trend

In 2014, the National Reference Center for Legionella Infections registered 133 cases of Legionnaire's disease including 12 deaths (9% lethality rate). Of the 133 cases, 107 (80.5%) were outpatients, 4 (3.0%) were hospital patients, and 22 (16.5%) originated from tourist accommodations. The probable source of infection was identified in 33 (24.8%) cases.



Facts

The international standard ISO/IEC 17021 specifies requirements which must be followed when auditing and certifying management systems. Every certification process utilized by TÜV AUSTRIA fulfills the requirements of this standard.

In 2015,
278
hospitals
opened across Austria.

Of the stationary
emergency hospitals,
46%
implemented a general quality
model in 2012.

In 2012,
33 hospitals
(at least) planned
a model for hospital-wide
implementation

Source: BMG

Management systems for the healthcare industry

By certifying your management system, you are ensuring ongoing improvements and gaining the trust of your patients and partners.

The following management system certifications are extremely important in the healthcare industry:

Quality management

- EN 9001

With EN 9001 certification, you are paying special attention to the satisfaction of your patients and stakeholders, optimizing your processes, accounting for risks as well as opportunities and, therefore, sustainably increasing the competitiveness of your health facility.

- EN 15224

An EN 15224 certification places additional focus on, for example, outsourced services and the confidentiality and infrastructure necessities of your facility.

- QMS-REHA

Use this certification to show that you are continuously developing and permanently securing the transparency of processes and procedures and efficiently using resources to increase the quality of rehabilitation-specific services. This certification will also support you in developing reserve capacities for your facility.

- EN 13485

With this certification, you as a medical device manufacturer or service provider (e.g., for outsourced processes in the development, manufacturing and distribution of medical devices) are in compliance with European regulations for market entry while also satisfying the requirement of many suppliers for an industry-specific quality management system. With EN 13485 certification, you are paying special attention to customer requirements and risk management.

Environment

- EN 14001

With environmental management system certification, you are indicating to your patients and stakeholders that you have an environmentally conscious and sustainable outlook. Furthermore, analyzing environmental impacts and implementing commensurate measures will help to reduce costs, optimize operational processes, and minimize risks.

Working safety

- OHSAS 18001 / ISO 45001

An Occupational Health and Safety Assessment Series (OHSAS) 18001 certification demonstrates that your health facility is socially responsible. You take action to prevent accidents and unsafe situations and thus significantly contribute to legal compliance in this regard.

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Training

TÜV AUSTRIA Academy – Your Training Partner for the Healthcare Industry

Health workers are confronted with a variety of standards and regulations that often change. Which is why the following principle applies: stagnation means regression! Ongoing training ensures, among other things, the protection of patients and legal compliance.

The TÜV AUSTRIA Academy is the training and further education center of the TÜV AUSTRIA Group that can provide your employees with practical courses on the topics of healthcare, medical devices, pharmaceuticals, and food safety. We also offer in-house seminars for medical technicians, procurement departments, and care services – we bring further education to you.

Our work focuses on the organization of qualified courses

and seminars as well as the preparation of specialist publications on the topics of safety, technology, the environment, and quality. Our training events and publications focus on the most up-to-date information and practical applications. A team of presenters made up of experts and practitioners from all departments of TÜV AUSTRIA as well as renowned companies and institutions guarantee this.

The TÜV AUSTRIA Academy also hosts the annual TÜV AUSTRIA Medical Devices Day: an industry event for certified medical device consultants and certified quality & regulatory affairs managers.

Seminars on the topic of medical devices

- **The Austrian Medical Device Directive (1 day, 8 hours)**
Installing, operating, using, and maintaining medical devices in health facilities
- **Periodic tests and inspections after commissioning electrical medical devices (1 day, 8 hours)**
EN 62353
- **Planning, installing and installing high current systems in hospitals (1 day, 8 hours)**
ÖVE E8007
- **Technical safety officers in healthcare facilities (4 days, 30 hours)**
Roles, rights, and responsibilities
- **The Austrian Medical Devices Law and its regulations (1 day, 8 hours)**
Procurement, application, maintenance and testing of medical devices
- **Medical gas pipeline systems in healthcare facilities (1 day, 8 hours)**
Requirements from EN ISO 7396 and RL 93/42/EEC
- **Training course for certification as risk manager for medical IT networks (3 days, 24 hours)**
EN 80001-1 - Application of risk management for IT networks with incorporated medical devices. Participation in the certification examination is recognized with a personal certificate from TÜV AUSTRIA CERT GMBH.

Info and booking:

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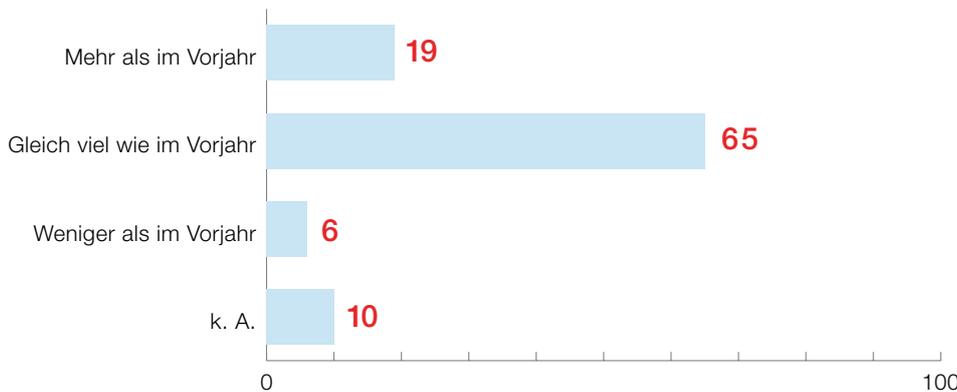
- **Lighting – safety lighting**



The entire list of courses can be found at: www.tuv-akademie.at/medizintechnik

2016 further education editions

Sample: 500 local companies, > 20 employees



Trend

According to Statistik Austria, the demand for advanced training is on the rise.

Source: MAKAM Research

STUFFS
WIND ENERGY FIRE PROTECTION
AUDIT OCCUPATIONAL SAFETY IMPACT ASSESSMENT
LIFTING TABLE FACILITY TESTS EXPLOSION PROTECTION MEDICAL PRODUCTS
DISPERSION CALCULATIONS ISO FURTHER EDUCATION ACOUSTIC EMISSION TESTING
PRE-SHIPMENT INSPECTION TELECOMMUNICATIONS ANALYSIS OF MACHINERY CONDITIONS
SURVEILLANCE LEAK TESTING SAFETY CERTIFICATE CONTRACTOR MRA-EU
CERTIFICATION WORKPLACE EVALUATIONS MATERIAL TESTING TYPE APPROVAL
CRANES PRESSURE EQUIPMENT ISM CONSULTING CONSTRUCTION ENGINEERING
STRUCTURAL INTEGRITY ENERGY CERTIFICATE ENVIRONMENT PROTECTION
OIL&GAS PLANT SAFETY 2006/42/EG CRANES, LIFTS, GATES EQUIPOTENTIAL BONDING EN 500
CABLE WAYS TYRE TESTING FOOD STUFFS MACHINERY, LIFTING & HANDLING
TESTING BODY INTERNAL INSPECTION PRODUCT SAFETY LIGHTNING PROTECTION
SPORTS PERSONAL PROTECTIVE EQUIPMENT LIGHTNING PROTECTION ISO 2006
EMC PERSONAL PROTECTIVE EQUIPMENT LIGHTNING PROTECTION ISO 2006
BOATH SAFETY EXPLOSION PROTECTION ELECTRICAL ENGINEERING
CONFORMITY DAMAGE INVESTIGATIONS TRAINING STEAM BOILER
FURNITURE TESTING GAS EMISSIONS SAFETY CATCH INSPECTION TYPE APPROVAL ROPEWAY SYSTEMS
ELECTRICAL ENGINEERING RECYCLING TRANSPORT PIPELINES THERMAL IMAGING
WELDER QUALIFICATION TRAINING ISO 14001 GAMES PLAYGROUND, SPORTS & LEISURE HEALTH
IT-SECURITY QUALITY MANAGEMENT EMAS-VO DECOMPRESSION CHAMBERS
STRESS-STRAIN MEASUREMENT PRESSURE PAPER PLANTS ESCALATORS WATER SLIDES
METALLOGRAPHIC INSPECTIONS RECYCLING EMC-INFLUENCE STORAGE INTEGRITY
ELEVATOR TECHNOLOGY WHEEL & RIMS EMS DURABILITY SUPERVISOR WELDER QUALITY
EN 14001 FIRE PROTECTION QUALITY MANAGEMENT EN 50060 DEFECTOLOGY
INSPECTION BODY RISK TECHNOLOGY PRESSURE EQUIPMENT TESTS ALC
PERSON CERTIFICATION VEHICLE INSPECTION ALI
TECHNOLOGY CALFACTOMETRY MATERIALS
PRESSURE ENERGY CERTIFICATE
ASSEMBLY MONITORING
CONSUMER ELECTRONIC
AUTOMOTIVE TECHNOLOGY
LAW & ENGINEERING
GREENHOUSE GAS
IMMUNITY TESTING
NOTIFIED BODY
SAFETY SPECIALIST IFS
MATERIAL FATIGUE
HIGH VOLTAGE SYSTEMS
STRUCTURE TESTING EN 1090
IGNITION PROTECTION
SAFETY ASSURANCE
NOISE CONTROL
PML NOTIFIED BODY
ACCREDITED
CONSTRUCTION
ENVIRONMENTAL
ENGINEERING & DESIGN
LAW
MEDICAL
PIPELINES MEASUREMENT
NON-DESTRUCTIVE TESTING
FLAT BOTTOM TANKS
FOR USE TESTED LIGHTNING PROTECTION
AIRBORNE POLLUTANTS
EQUIPMENT NOISE
PERSONAL PROTECTIVE EQUIPMENT

Both men and women are implied when personal pronouns are used in this folder.

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