

Medical Devices

Technical safety
protects your patients



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. Simply safe.

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

- Periodic safety testing of medical devices	04
- Calibration of medical devices (MTK)	04
- Inspection of high-voltage systems in health facilities	05
- Inspection of medical gas pipe installations	05
- Hygiene testing for bedpan disinfection	07
- Thermoelectric measurement of small steam sterilizers	07
- Consistency testing of X-ray equipment	07
- Technical safety officer	08
- Safety expert	08
- Reports and incident investigation	09
- Software for maintenance and facility management	09

Other services from the TÜV AUSTRIA Group:

- Preventive hygiene concepts	13
- Drinking water hygiene	15
- Management system certifications	17
- Training	18

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 well-being 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.

The safety and the flawless function of technical medical devices must be tested and ascertained in the form of “technical safety inspections” on a regular basis 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.

TÜV AUSTRIA offers on-site calibration of medical devices

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

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.

The estimated number of
medical devices
on the **European market**
ranges between **500,000** and
one million, with approximately
8.000 different types.

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.

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

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.

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.

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

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

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

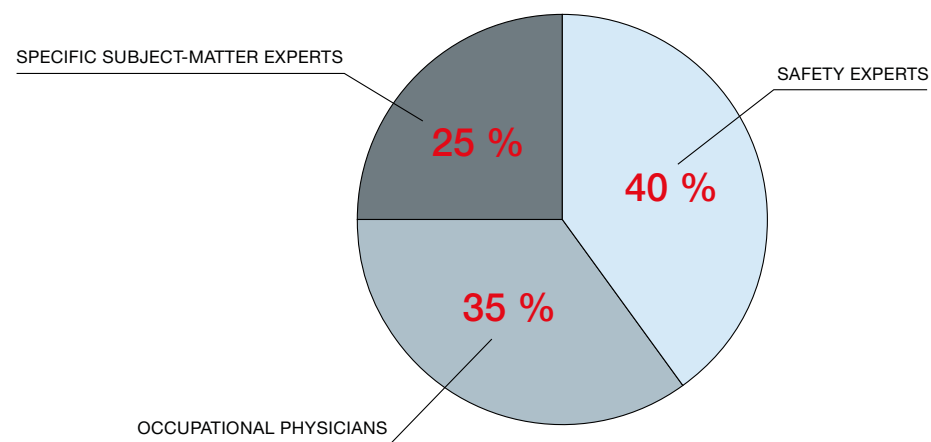
Safety expert

Workers in healthcare facilities are exposed to numerous hazards: transmitted diseases, blood, and hazardous materials can threaten nursing and cleaning personnel and doctors.

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.

The purpose of preventative services, namely the use of safety experts, is to advise the employer with the goal of minimizing risks.

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



Source: acc. to § 82a (5) ASchG

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.



Reports and incident investigation

The risk of incidents or close calls in connection with medical devices or technical equipment (medical products, electrical systems etc.) must be minimized in principal. Should something nevertheless happen, the cause of the

incident must be thoroughly investigated. TÜV AUSTRIA experts will help you determine the cause(s) 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.

are increasingly challenged with regard to scheduling and cost analysis.

In addition to the documentation requirements under the Austrian Medical Devices Law, technical departments

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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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.

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

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.

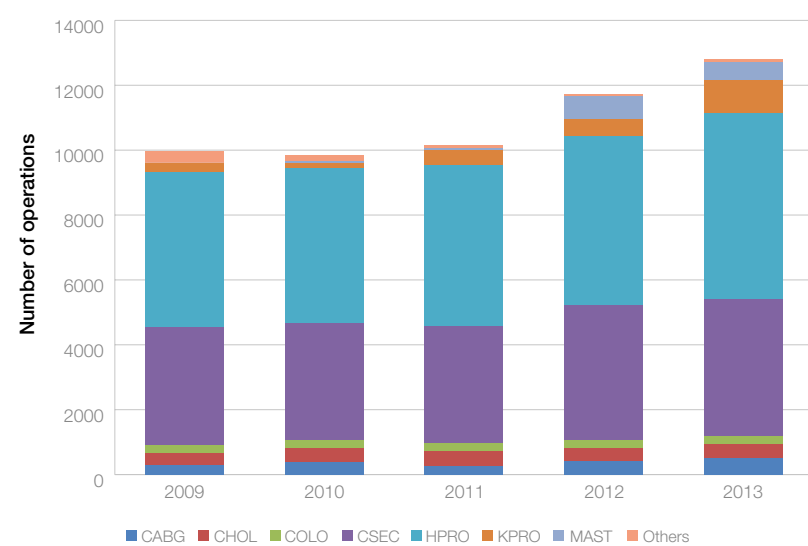
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Nosocomial infections in Austria

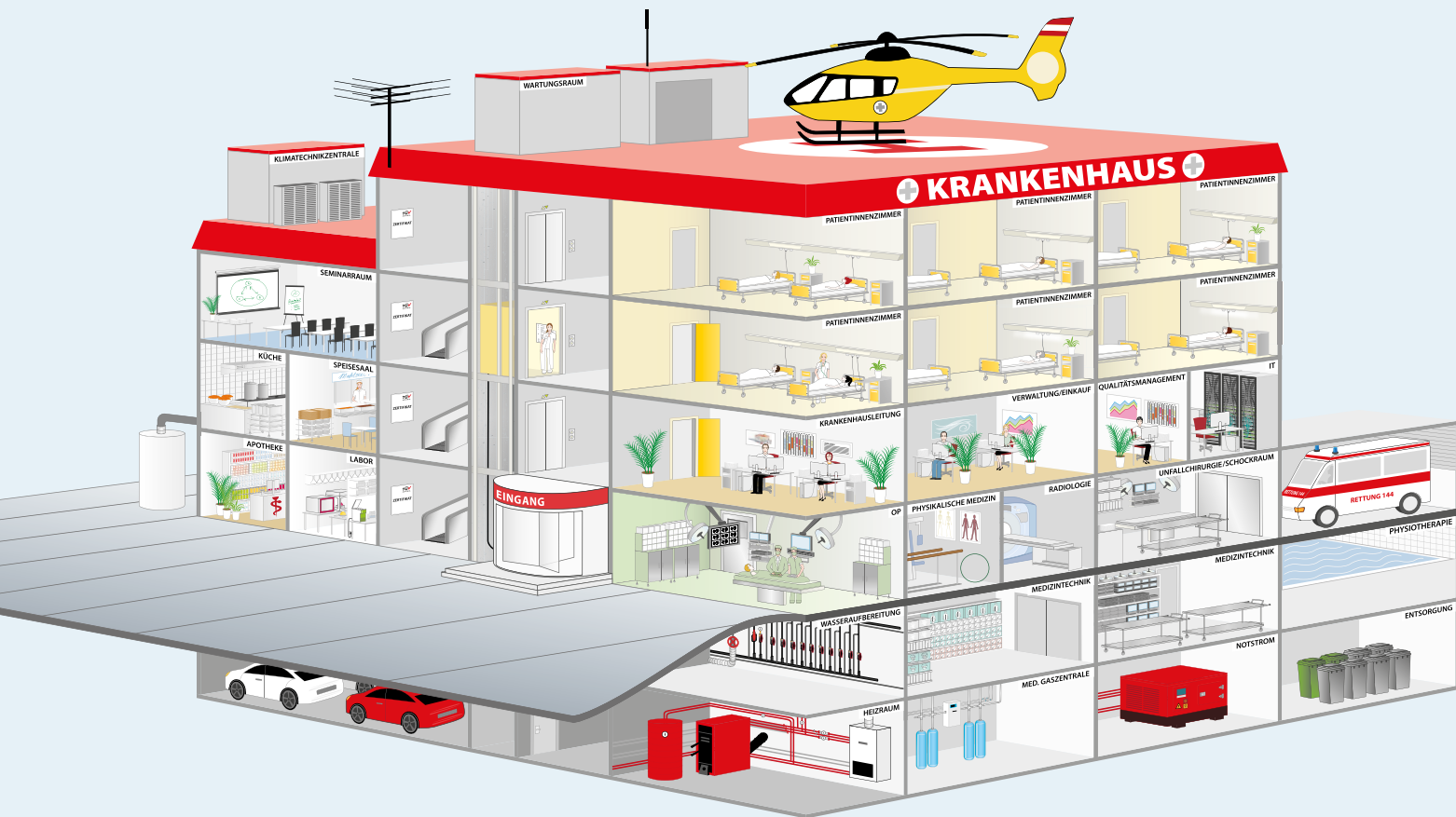


CABG=coronary artery bypass surgery, CHOL=gallbladder surgery, COLO=colon surgery, CSEC=caesarean section, HPRO=hip prosthesis surgery, KPRO=knee prosthesis surgery, MAST=mastectomy

Source: BMGF

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.



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.

Info and contact:

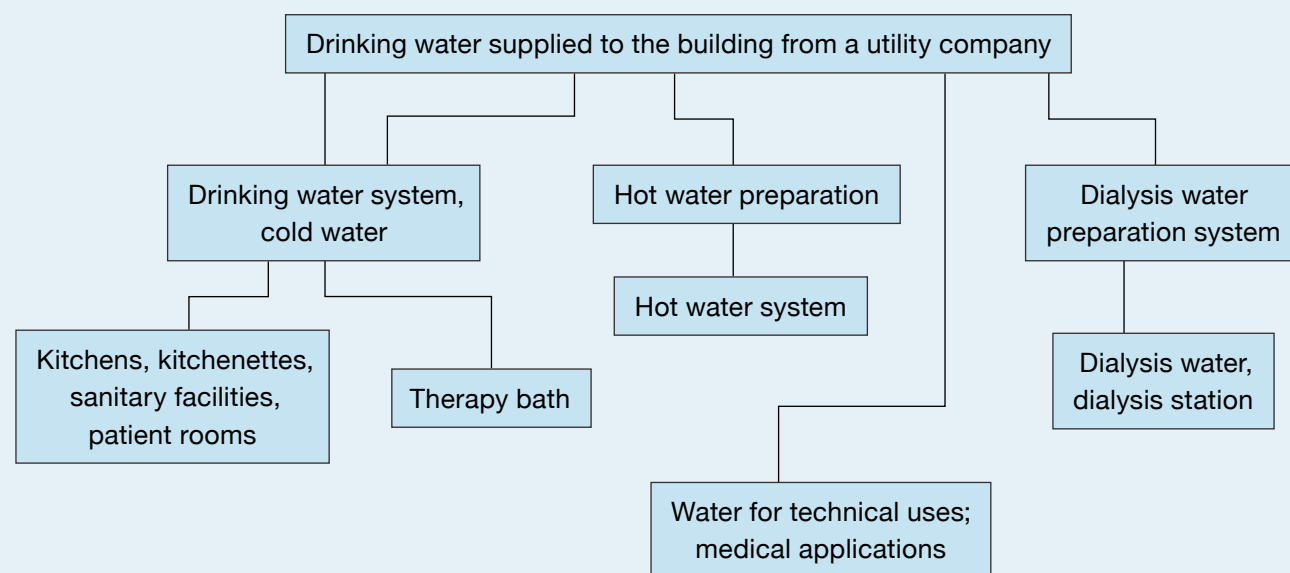
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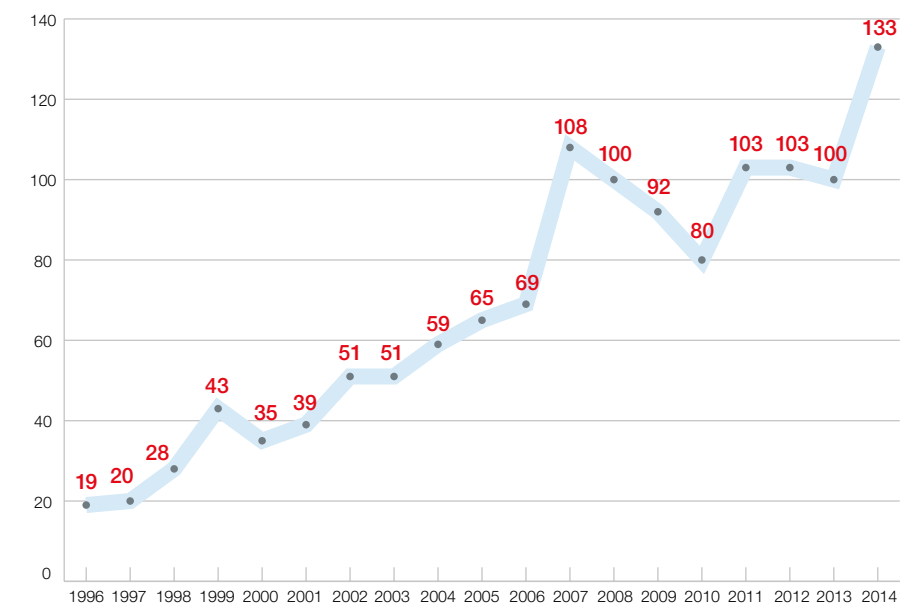
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Incidence of Legionnaire's disease in Austria, 1996 – 2014



n = 1298

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.

Source: AGES



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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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



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
- **Medical gas pipeline systems in healthcare facilities (1 day, 8 hours)**
Requirements from EN ISO 7396 and Directive 93/42/EEC
- **Periodic tests and inspections after servicing electrical medical devices (1 day, 8 hours)**
ÖVE/ÖNORM EN 62353
- **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. Successful participation in the certification examination is recognized with a personal certificate from TÜV AUSTRIA CERT GMBH.
- **Planning, installing and testing high-current systems in hospitals (1 day, 8 hours)**
ÖVE/ÖNORM E8007
- **Risk management for medical devices in IT networks acc. to EN 80001-1 (1 day, 8 hours)**
Overview seminar
- **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
- **Emergency lighting – safety lighting (1 day, 8 hours)**
in buildings with crowds, hospitals, and places of work

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

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.

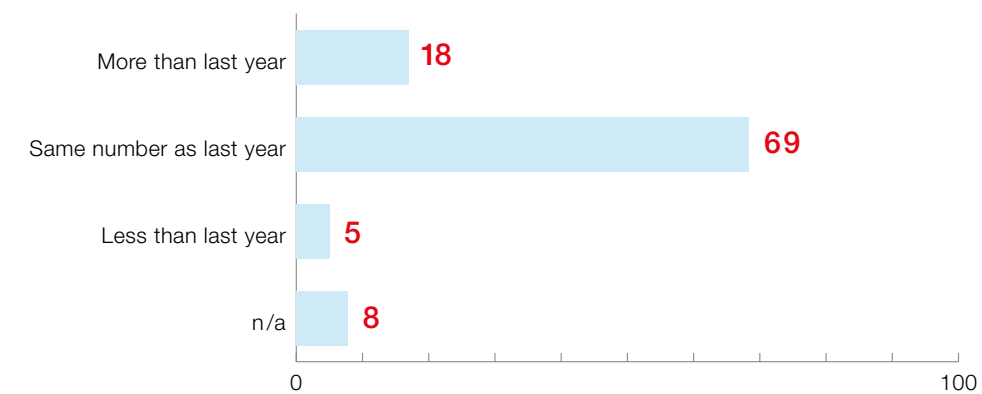
The TÜV AUSTRIA Academy is the training and further education center of the TÜV AUSTRIA Group that can provide your employees with practical courses on the topics of healthcare, medical devices, pharmaceuticals, and food safety. We also offer in-house seminars for medical technicians, procurement departments, 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: a meeting for the entire medical devices industry, in particular certified medical device consultants and certified quality & regulatory affairs managers.

2017 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
INTERNAL INSPECTION PRODUCT SAFETY LIGHTNING PROTECTION
SPORTS & LEISURE FITNESS FOR USE TESTED ISO 9001 APPROVED WELDER QUALIFICATION
EMC PERSONAL PROTECTIVE EQUIPMENT LIGHTNING PROTECTION ISO 2006
EXPLOSION PROTECTION ELECTROSTATIC DISCHARGE
DAMAGE INVESTIGATIONS TRAINING
SAFETY CATCH INSPECTION TYPE APPROVAL STEAM BOILER
ELECTRICAL ENGINEERING RECYCLING TRANSPORT PIPELINES THERMAL IMAGING
WELDER QUALIFICATION TRAINING ISO 14001 HEALTH & SAFETY
IT-SECURITY QUALITY MANAGEMENT EMAS-VO DECOMPRESSION CHAMBERS
STRESS-STRAIN MEASUREMENT PAPER PLANTS ESCALATORS WATER SLIDES
METALLOGRAPHIC INSPECTIONS OFF-SHORE STORAGE INTEGRITY
ELEVATOR TECHNOLOGY WHEEL & RIMS PLAYGROUND, SPORTS & LEISURE HEALTH & SAFETY
EN 14001 FIRE PROTECTION QUALITY MANAGEMENT SUPERVISOR WELDER QUALIFICATION
INSPECTION BODY RISK TECHNOLOGY PRESSURE EQUIPMENT TESTING EN 50639
PERSON CERTIFICATION VEHICLE INSPECTION ALC EN 50639
TECHNOLOGY COLFACTOMETRY MATERIAL TESTING
PRESSURE ENERGY CERTIFICATE EN 50639
ASSEMBLY MONITORING EN 50639
CONSUMER ELECTRONIC EN 50639
AUTOMOTIVE TESTING EN 50639
LAW & ENGINEERING EN 50639
GREENHOUSE GAS EN 50639
IMMUNITY TESTING EN 50639
NOTIFIED BODY EN 50639
SAFETY SPECIALIST IFS EN 50639
MATERIAL FATIGUE EN 50639
HIGH VOLTAGE SYSTEMS EN 50639
STRUCTURE TESTING EN 1090 EN 50639
IGNITION PROTECTION EN 50639
LIABILITY ASSURANCE EN 50639
NOISE CONTROL EN 50639
PML NOTIFIED BODY EN 50639
ACCREDITED EN 50639



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

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www.tuv.at/medizintechnik