

Funke
MEDICAL

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MASTER NEW
CHALLENGES

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Andreas Funke

CEO of Funke Medical AG

Dear reader,

With the third edition of our Funke Medical Magazine we give an insight into current topics of the MDR 2017/745 and how we want to solve the problems together with our customers.

Furthermore, we give you an update on the latest developments of Funke Medical and its products.

Paradigm change in medical device law!

Each company that wants to launch medical devices in the future must fulfil the requirements of this new legal framework.

One thing is for sure:

What once began as a patient safety debate under the pressure of the breast implants scandal will completely change the tectonics of the medical device industry, because the almost 200 pages of the Medical Device Regulation (MDR) provide for changes in

every stage of the CE marking, that a medical device must pass through:

- from the technical documentation
- development
- clinical evaluation up to certification
- market surveillance and product identification

Questions upon questions?

- But how do medium-sized industrial companies and commercial enterprises cope with this situation?
- What do the companies have to be prepared for?
- What consequences will MDR have for the market and future innovations?
- How do companies position themselves strategically?

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Companies need more money in reserve to bring new products on the market. This applies to the industry, as well as to the trading partners.

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This is the subject of this issue and we would also like to answer these questions in person. Because only through cooperation and partnership can these requirements be met. This already starts with the interface of the backtracking systems.

It is safe to say:

Companies need more money in reserve to bring new products on the market. This applies to the industry, as well as to the trading partners.

For the distributors that means:

- Responsible purchasing → Suppliers who do not comply with the MDR are out! (CE marking according to MDR, clinical evaluation according to MEDDEV 2.7.1 rev. 4, backtracking with UDI-code, designation of a qualified person, ...)
- Clean-cut process descriptions according to ISO 13485:2016
- After-market-surveillance in cooperation with the industry
- Products that have not been recertified by the manufacturer may no longer be used

Many people describe the **MDR as the biggest obstacle** in the industry. I think that it is a great opportunity to protect the market from the outside and to stop backyard workshops' activities by quality surveillance and we have chance to focus on the quality of our products again.

I would like to invite you to ask us at any time if anything might be unknown or inconclusive.

Thank you for your continued support and partnership.

Andreas Funke
- CEO -

All we had to do was flip the switch

25. Mai 2017

MDR 2017/745

Funke Medical AG has met all requirements since the new European Medical Device Regulation came into force.

After more than four years of negotiations, on **25 May 2017**, Regulation (EU) 2017/745 of the European Parliament and of the European Council on medical devices (amending Directive 2001/83/EC, Regulation (EC) no. 178/2002 and Regulation (EC) no. 1223/2009) and Regulation (EU) 2017/746 of the European Parliament and the European Council on in vitro diagnostic medical devices came into force.

With some exceptions, the medical device regulation will apply from **26 May 2020** and the in vitro

diagnostic regulation will apply from **26 May 2022**.

The two regulations will replace the Medical Devices Directives 90/385/EEC and 93/42/EEC as well as Directive 98/79/EC on in vitro diagnostic medical devices. They are immediately applicable in the member states of the EU and therefore do not need to be converted into national laws. Nevertheless, extensive adjustments to national medical device laws will be required.

Strategically
smart approach

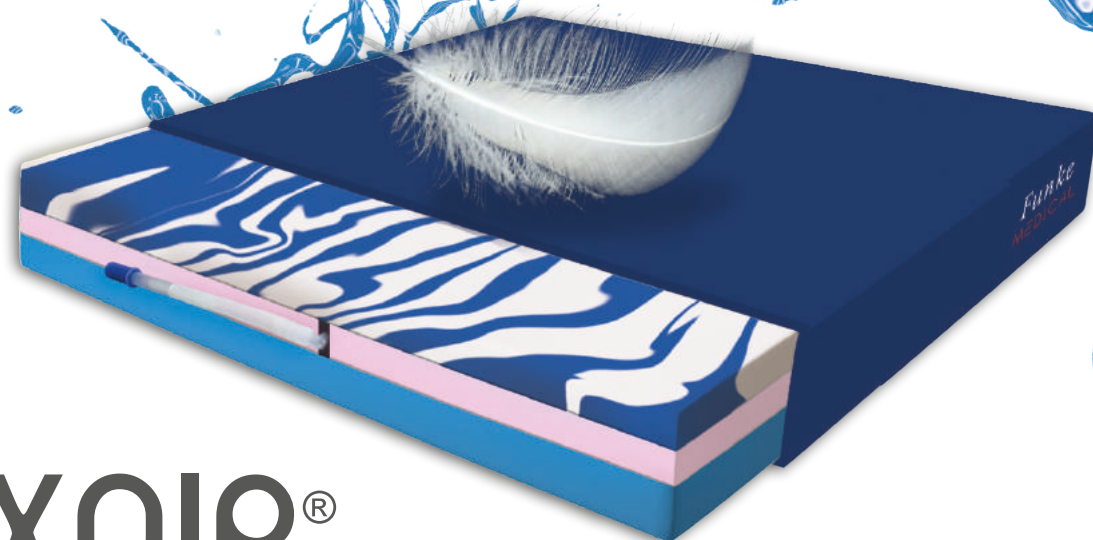
The key changes in the new Medical Device Regulation (MDR) include crucial points affecting Funke Medical AG. These include the introduction of an additional control procedure, the specification of the clinical evaluation requirements and the improvement of the identification and traceability of products through the implementation of a unique device identification number (UDI).

“

The EU regulations therefore not only require extensive adjustments to national law, but also present us as manufacturers with considerable challenges in terms of practical implementation”, reports Andreas Funke, CEO of Funke Medical AG, adding: “Funke Medical AG has met all requirements since the new Medical Device Regulation 2017/745 came into force in May 2017 owing to the fact that we counter the significant differences between the regulations and the constant changes to European and international law at an early stage. When the MDR came into force, we were already completely prepared and basically just had to flip the switch.

”





- AIR-CELL SEAT CUSHION -
For active wheelchair users!

PRODUCT INNOVATION

Funke Medical AG is delighted to present the *XAIR® hybrid* seat cushion, a brand-new innovation from the decubitus therapy system product range for **decubitus prophylaxis and therapy up to and including stage 4 (according to Prof. Seiler/EPUAP)** which is explicitly aimed at active wheelchair users.

The *XAIR® hybrid* is a ground-breaking decubitus therapy air-cell seat cushion which can also be used for **pain therapy**. The innovative seat cushion can be individually adjusted for **ideal sitting comfort** via a special valve and provides optimal pressure relief for the sacrum and the ischial tuberosity through a three-chamber construction with hyperelastic foam cores. Thanks to the valve which is easily operated

by one hand only, wheelchair users are also able to quickly and simply adjust their cushion according to the changes of the external air pressure conditions. Adjustment requires **no additional equipment** such as an air pump which is often required by many other air-cell seat cushions.

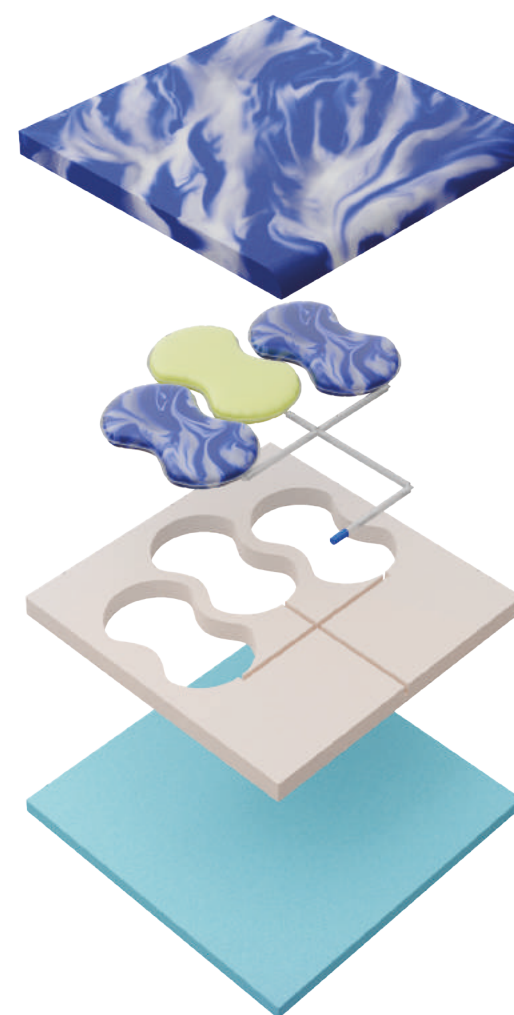
Another benefit is the fact that there is **no malfunction risk** with the *XAIR® hybrid*. The user will never have to sit on a deflated cushion, as may be the case with purely air-cell seat cushions without a foam filling.

Optimal climate control

The revolutionary GELTOUCH® technology which enables a significantly better microclimate than many other gel cushions or air-cell seat cushions also has the benefit that it prevents strong perspiration owing to the cooling effect of the GELTOUCH® foam. The watertight and breathable cover can be removed and washed at up to 60°C. A special mesh³ fabric also provides ideal climate control.

Further properties

The special anti-slip bottom prevents the seat cushion from slipping off the wheelchair. Owing to the **low weight** – which is unusual for these types of cushions – as well as the **practical handle**, the *XAIR® hybrid* seat cushion is very easy to transport. As is the case with all Funke Medical decubitus therapy seat cushions, the *XAIR® hybrid* is also available in twenty different sizes, providing a suitable solution for every wheelchair user.



Another quick overview
of the key benefits of the
XAIR® hybrid:

- Outstanding pressure relief
- Optimal microclimate through breathable materials
- Cooling effect owing to the unparalleled GELTOUCH® technology
- Watertight, washable cover
- Anti-slip bottom
- Much lower in weight than conventional air-cell seat cushions
- User-friendly: valve with one-handed operation
- No risk of malfunction
- No pump or other equipment required
- Quick adjustment to external air pressure conditions
- Available in various sizes

Funke Medical Academy

Update your professional skills!



24 hours
Worldwide
All devices

Training made easy

According to national and international legislation, all professional groups in the health sector are obliged to be trained regularly.

This also applies to people who work with medical devices that provide patients with preventive and therapeutic support. Funke Medical AG is breaking new ground in this area and is offering these required training courses as free online certificate courses as part of the Funke Medical Academy.

All training courses of this innovative added-value concept are based on the latest scientific findings and are constantly updated. The courses, which are offered in German, English and Spanish, were developed by educators with a scientific background.



Integration of cooperation partners

The Funke Medical Academy is aimed at distributors and care givers who receive the opportunity to undergo training and acquire the legally required certificates through this free offer.

The customers of Funke Medical AG also have the option to integrate their cooperation partners such as nursing services, retirement homes and hospitals into the training courses via a personal registration key, which can enhance their relationship with the company.

Taking courses from a distance

Registration for the Funke Medical Academy is very simple: the customers of Funke Medical AG receive a registration key for themselves and their cooperation partners, with which they can register and log in online at academy.funke-medical.de.

The course participants are guided through the learning material for the individual modules necessary to acquire the certificates in an interactive, multimedia-based way. There is a large number of training topics and it can be extended at any time.

Topics on the Funke Medical Academy syllabus include basic medical knowledge about decubitus, fundamentals on decubitus prophylaxis and therapy, and product training. Additional training courses such as the Medical Device Regulation 2017/745 module will be added soon.

academy.funke-medical.de



Do the course!



Pass the test!



Receive the certificate!



Done!

Certification in just a few steps

The individual modules and associated tests build on each other, thus dictating the order in which you work through them. A test can only be taken when you have fully completed the corresponding module. To pass a test, you need to answer at least 75 percent of the questions correctly.

Once all the modules have been completed and all the tests passed, you will immediately receive a certificate that can be submitted as proof for authorities or health insurance providers. This form of certification and recertification is required internationally by law and must be repeated annually.



SAFER QUICKER GENTLER

Did you know that in the event of a fire, you generally only have three minutes to escape the smoke and fire? Particularly for facilities such as clinics and retirement homes where managers are responsible for the fastest evacuation measures, a fire presents a dangerous challenge.

In the event of an evacuation, using conventional means such as rescue sheets and stretchers, which are often not fast enough at hand or sometimes completely missing, means that at least 4 to 6 rescuers are required to bring a person safely out of a building.

3 minutes



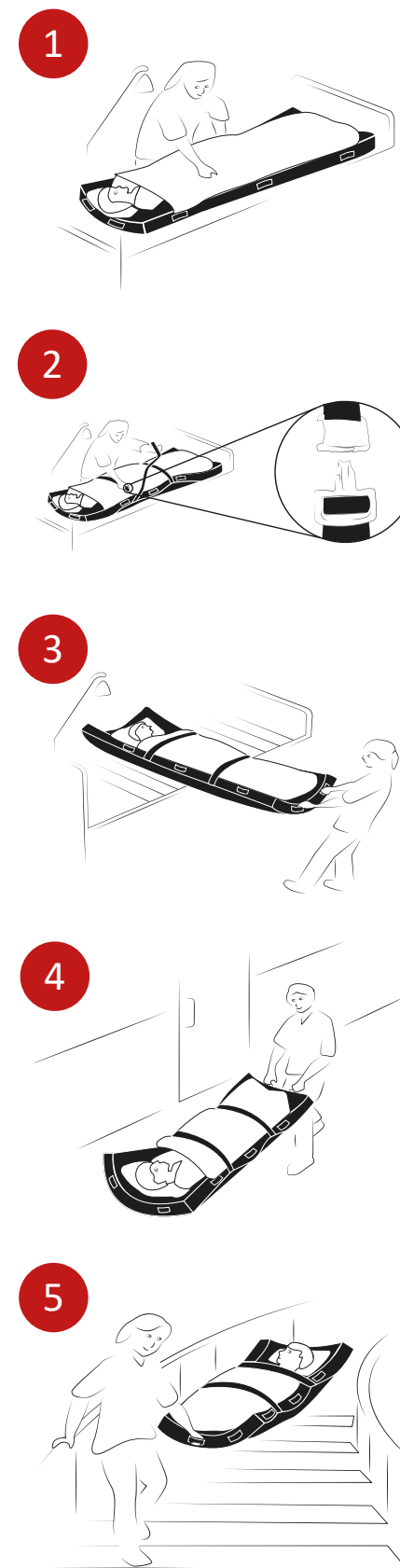
The “all-in-one” solution

This is where the EVAQ® decubitus therapy mattresses from Funke Medical AG can help. They feature an evacuation function so that patients can be evacuated by **just one person** in the event of a fire even when faced with stairs – and they can do so quickly, easily and without requiring complicated and time-consuming transfers to rescue sheets or stretchers.

Special safety straps with quick release fasteners located on the sides of the EVAQ® decubitus therapy mattress can be used to secure the person to be evacuated.

The mattress is equipped with frame reinforcement for added stability. Using the safety belts, the mattress envelops the patient comfortably. With the aid of the rescue handles on the cover, the rescuer can gently pull the mattress together with the person to be evacuated from the bed and transfer the person out of the building.

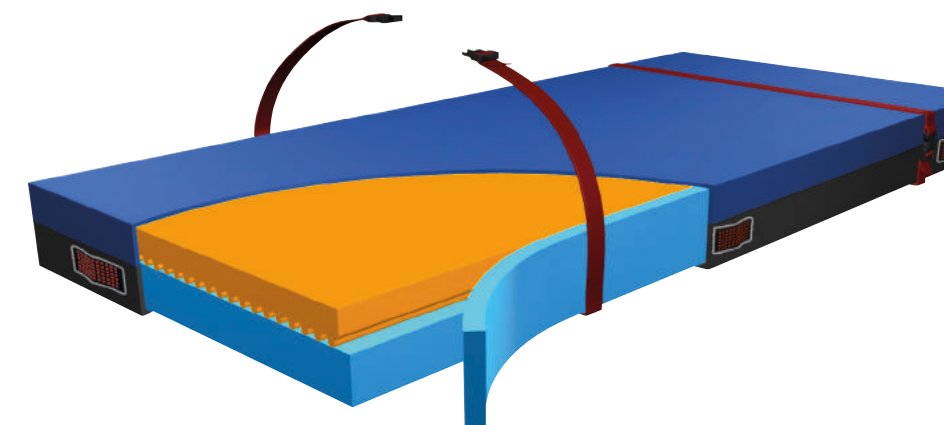
The special sliding material on the underside of the EVAQ® decubitus therapy mattress enables rapid evacuation via stairs as the mattress slides effortlessly down the steps. The duration per floor is **less than 60 seconds** when using an EVAQ® mattress.



Recognising a need

Increasing numbers of retirement homes and clinic managers are replacing their standard medical mattresses for Funke Medical EVAQ® mattresses in order to avoid any risks in the event of an evacuation.

By purchasing an EVAQ® mattress, you are buying more than just a high-quality mattress, since every EVAQ® mattress is also a decubitus therapy system, but you also receive peace of mind knowing that the rescue system is always with the patient, thus ensuring the fastest possible evacuation.



Another quick overview of the key benefits of the EVAQ® decubitus therapy mattress:

- Easy operation
- The evacuation system is always ready for use
- The evacuation system is always close at hand
- There is no need for time-consuming bed transfers
- Efficient: evacuation is possible through just one person
- Evacuation is possible via stairs
- Quick evacuation: less than 60 seconds per floor
- More cost-effective than buying a standard medical mattress and a separate evacuation system

Wave of Support and Assistance

In 2007, the lives of Markus Große-Boes and his wife Susanne were put through the wringer. During a [serious swimming accident](#) at their nearby pond, the Wulfen local broke two cervical vertebrae resulting in tetraparesis, in other words, an impairment of all four limbs.

At this time, Silvester, the couple's first son, was only ten months old, Markus Große-Boes was about to launch his own business as a horticulturist and landscape designer, and had already built a hall and a house for his small family on a plot in Dorsten-Wulfen.

Within a few seconds, the project was ruined and the life of the couple was turned upside down. "It was particularly difficult for my father to bear that I would now be bound to a wheelchair forever. But I was able to accept the situation as it is now [surprisingly well](#)", says Markus Große-Boes, who can no longer move his legs and fingers due to the cross-section.

Many helping hands

The pension provider enabled a fast, barrier-free conversion of the house and Markus Große-Boes did not allow the life-changing experience to get him down. "The [active and encouraging support I received from my family and friends contributed a great deal to this](#)", stated the hydraulic engineer, feeling grateful for being able to count on many helping hands, even during difficult times.

"After nine months of rehabilitation, it was finally time for me to transition from craftsman to office worker", said the 45-year-old and added: "I had worked as a bridge builder until the accident, and fortunately, my employer allowed me to work part-time at the water and shipping office following rehab."

Team sport with like-minded people

Not only did Markus Große-Boes opt for a speedy return to work, he also began playing wheelchair rugby one year after the accident. "This sport can [greatly facilitate and enrich the everyday life of a wheelchair user](#)", says the family man, whose younger son Dennis was born seven years ago. There are around 300 wheelchair rugby players throughout Germany who run this type of sport

and undertake long journeys for the weekly training sessions and to participate in tournaments. "But this effort is greatly worthwhile since team sport allows you to spend time with like-minded people and gives you the opportunity to pursue a suitable [sporting activity which is really fun](#)", emphasises Markus Große-Boes, who faces the everyday efforts of being a wheelchair user with a positive attitude.

GREAT SITTING COMFORT

"In terms of accessibility, a lot still has to be done particularly in rural areas, but we are seeing more and more aids on the market that make everyday life in a wheelchair much easier", says Markus Große-Boes.

"Through contact with the Funke couple, for example, I became aware of the special [wheelchair seat cushion developed by Funke Medical AG](#). These are not only very position-stable but also very soft and comfortable. The seat comfort is excellent and now that I use the seat cushion, I have [no more pressure sores](#)", says the Wulfen local – a clear recommendation for the products of Funke Medical AG – feeling pleased that they will continue providing assistance.



CAREER AT FUNKE MEDICAL AG

Machine and plant operator

As a medium-sized company, Funke Medical AG produces on a site measuring 17,800 square metres in total with the aid of over 100 employees – and that's just in Germany, namely in Raesfeld, North Rhine-Westphalia.

“We know that we can only guarantee the quality required by our customers with the aid of qualified, motivated and dedicated employees. This is why we are always looking for dynamic people who want to support us within the team”,

reports Andreas Funke, CEO of Funke Medical AG.

We are therefore presenting the profession of **machine and plant operator**, one of the six training professions within the company.

Brochure at

funke-medical.de/en/career

Machine and plant operators manage production machines and plants

Machine and plant operators set up processes, check machine functions using test benches and commission machines.

These include, for example, machine tools, textile machines and printers or foam processing plants. They monitor the production process as well as managing and monitoring the material flow. In addition, machine and plant operators inspect and maintain machines at regular intervals in order to guarantee their operational state.

For example, they top up the oil, coolant and lubricant as well as replacing wear parts such as seals, tools, cutting equipment, filters and hoses.



Training requirements and training course

To work as a machine and plant operator, you must bring with you special care, attention, decision-making skills, capacity for teamwork, technical understanding and technical skills, and have at least a secondary school leaving certificate.

Machine and plant operator is a **two-year recognised vocational training** of the Chamber of Industry and Commerce. Funke Medical AG offers its trainees cooperation and support in a dynamic team, a modern workplace, development opportunities in the company as well as interesting and versatile projects.

Should you choose Funke Medical AG as a training company, you can expect a comprehensive education. In addition, trainees have a permanent contact person for training-related queries. Workwear for workers is provided by Funke Medical AG. After training, there will be a **possibility of permanent employment**.

Funke Medical AG offers more than just medical technology

Funke Medical IT Solutions provides comprehensive hardware and software solutions for every company.

In 2018, Funke Medical AG founded the IT company Funke Medical IT Solutions GmbH. This strategic move arose from the need to retain information technology expertise in the company, as this knowledge is a strict requirement for Funke Medical AG as a certified medical technology manufacturer in accordance with ISO 13485.

Complicated industry processes, all of which are subject to traceability have to be mapped in the network on a daily basis and stored for at least ten years. When the Medical Device Regulation 2017/745 came into force in May 2017, this traceability became even more crucial.

The idea to establish their own IT company was quickly implemented with the experienced managing directors, Ingo Klug and Thorsten Ortmeier. It not only serves its parent company but is also an IT supplier for other companies in the region, the Ruhr area and sometimes even beyond.

“IT should serve your business and people – not the other way around. We have an eye on all your IT processes – from the small parts to the big picture.”

Ingo A. Klug, Managing Director Funke Medical IT Solutions GmbH



The Funke Medical IT Solutions GmbH portfolio ranges from IT infrastructure and IT support to ERP systems and IT security.

An IT infrastructure is the foundation for every company. Funke Medical IT Solutions GmbH regularly analyses the individual IT requirements of its customers so that adjustments can be made in a needs-based manner, thus allowing IT-supported processes to always be mapped quickly and efficiently.

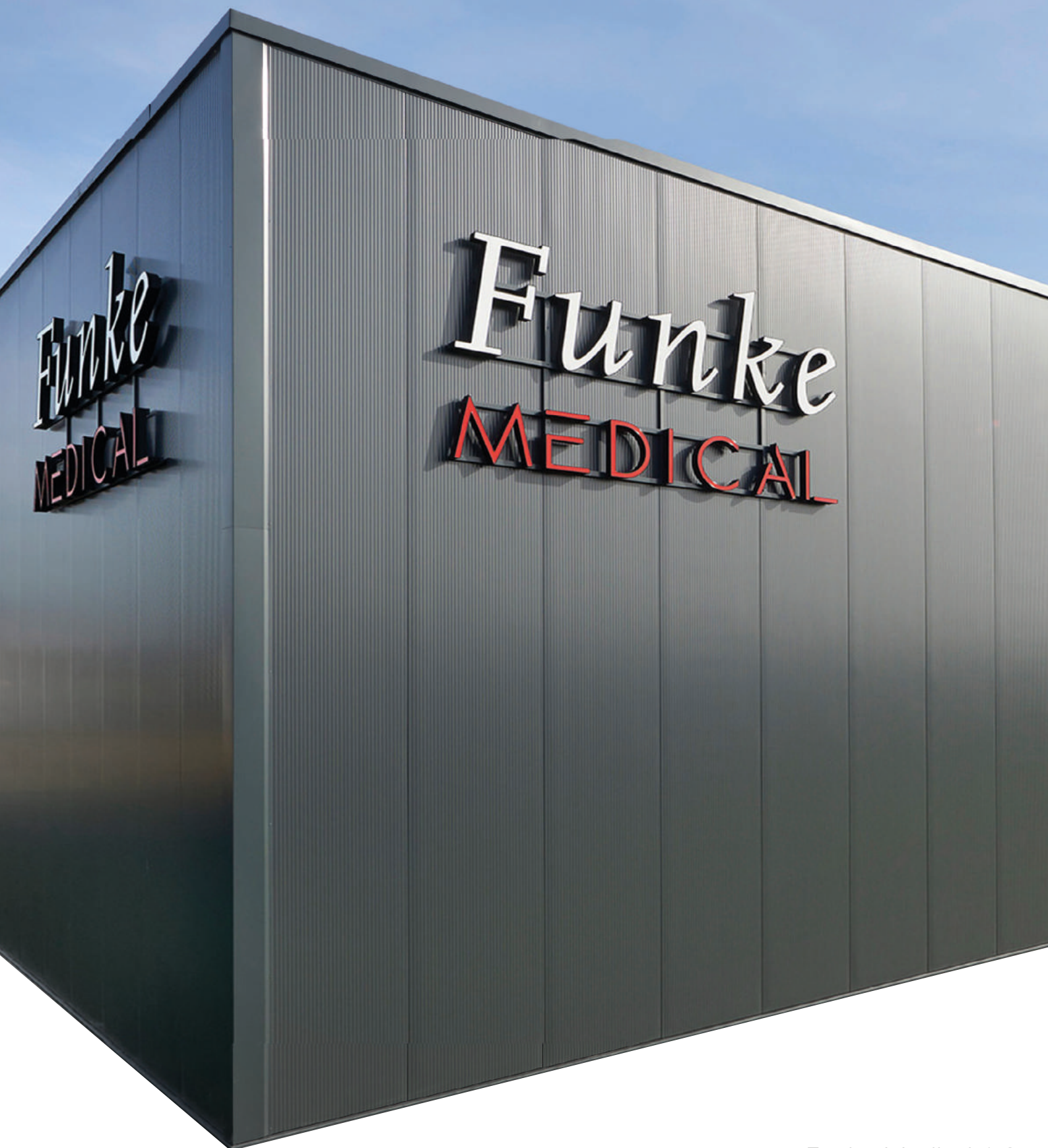
This also includes providing comprehensive support during the selection of suitable hardware and software, as well as setting up server peripherals and data backup. Individual IT support either on site or via telephone ensures that IT processes run smoothly and any issues can be rectified in a flash. As a partner of PRTG, a manufacturer of monitoring software, IT Solutions is able to offer round-the-clock monitoring so that any malfunctions can be prevented or minimised through proactive problem detection.

Another pillar is its role as a SAGE DEVELOPER PARTNER. SAGE offers ideal merchandise management and production control software (ERP systems) for small and medium-sized commercial and industrial enterprises.

“Consultations for the implementation of new ERP software always go hand in hand with a process and needs analysis for the customer. We offer telephone support for SAGE and additional individual solutions”, reports Thorsten Ortmeier.

The young company provides a special offer as a SOPHOS partner. With SOPHOS, companies are able to protect their IT against viruses, Trojans and hackers in an effective, customised manner.

The media design sector is another pillar of this experienced team. The portfolio is topped off by websites, online shops linked to merchandise management and app programming. Founding IT Solutions has proved to be a strategically important move for Funke Medical AG.



Funke Medical AG

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