Comes into effect in May 2020:

TRACOE medical is preparing for the Medical Device Regulation (MDR)

- **Four successful audits and certifications in one week**
- **EU Regulation calls for major changes in the medical technology industry**
- **A major challenge for small and medium-sized enterprises**

Dr Thomas Jurisch, Managing Director
TRACOE medical GmbH

Nieder-Olm, September 2018 – TRACOE medical GmbH, a leading developer and manufacturer of medical devices in the fields of tracheostomy and laryngectomy, is rigorously preparing for the implementation of the Medical Device Regulation (MDR), which definitively enters into force in May 2020. In addition to this, TRACOE has initiated two major programmes, which will ensure MDR compliance by May 2020. There are good reasons why the company is making this effort: “The new regulation involves the industry’s most drastic change in decades - presenting tremendous challenges, especially for small and medium-sized enterprises, because the regulatory expense is so high that there is a risk this will present insurmountable hurdles for niche products and, in particular, for small medical technology manufacturers”, TRACOE medical GmbH’s Managing Director Dr Thomas Jurisch explains. “And as these are our core issues and we intend to position ourselves optimally for the future, we have made the conscious decision to implement the new regulations as quickly as possible”.

In principle, it is to be welcomed that the aim of the EU regulation, which entered into force in 2017, was to provide greater transparency and safety for patients, Dr Jurisch said: “However, the significant increase in red tape is making implementation a challenge for the entire industry”. Under the regulation, all processes involving medical devices will be substantially more extensive than before, marketing authorisation more complex and controls significantly increased. There is also the risk of there being less innovation, because fulfilling the MDR requirements ties up resources and the development of medical devices is generally subject to more regulations.

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Early implementation at TRACOE

TRACOE medical already started planning for the MDR a year ago and, following the successful audits in May, is now implementing the specified measures within the framework of two major programmes. By application of the MDD (Medical Device Directive), the company concluded the European Medical Devices Directive currently in force. It also provided services in accordance with the regulations for EN ISO 13485:2016, which governs the requirements for a comprehensive quality management system for the design and manufacture of medical devices. TRACOE medical also completed the MDSAP (Medical Device Single Audit Program), making the cannula manufacturer the first company to be certified by the competent team of auditors. And last but not least, TRACOE medical also had the recently opened logistics centre approved with the appropriate TÜV (Technical Inspection Authority) certification. Dr Jurisch: “As we have developed an ethos for regulatory matters and have a well-established project management system, we have already been able to successfully implement the first measures of the MDR, which we are very pleased about”.

Challenges for the industry

Like the competent trade associations, TRACOE managing director Dr Jurisch can also see problems, particularly as regards the very short three-year transition period. The numerous changes for the inspection bodies (“Notified Bodies”) cause bottlenecks there. The result is long waiting times for certification dates and the risk that the products are not certified on time. Smaller and new manufacturers, in particular, are also confronted with the problem that “Notified Bodies“ frequently no longer take them on as new customers. Experts anticipate that, in future, certification bodies will even disappear, while the number of products to be controlled will significantly increase. “It is therefore unlikely that there will be sufficient certification bodies available by the end of the period“, Dr Jurisch continued. Furthermore, the conditions necessary for successful implementation of the MDR still need to be created at EU level (EUDAMED). Doubts are growing that this will happen in time.

Consequences for manufacturers and patients

Delays in product approval make the marketing more difficult and can therefore lead to economic loss and, in some circumstances, even jeopardise business activities. “Because of the huge regulatory expenses involved, there is also the risk that niche products and innovations will become uneconomical. For us this means checking in each individual case whether to selectively withdraw individual products from the market“, says Dr Jurisch. If the regulatory expense under the MDR increases even further in the future, this will inevitably lead to price increases: “The implementation of the regulation is manpower-intensive and therefore costly. The high demands on resources increase the costs still further. The result is the same for all manufacturers: the same quality becomes more expensive or - vice versa - there is less quality for the same money”. Particularly for a medium-sized premium supplier, who offers “Quality made in Germany“ and invests heavily in research and development, this constitutes an aggravating factor in economic terms.

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TRACOE echoes the calls from the associations

"The implementation of the new EU-wide regulation is not yet feasible", Dr Jurisch sums up the status quo: "This is why the associations are calling for pragmatic solutions to be found at EU-level - NAKI (National Working Group for the Implementation of the MDR and IVDR) is already working on this. We can confirm, as a company affected by it, that there is an undeniable need for action here - particularly because we have already begun implementation".

More information on the entire TRACOE brand portfolio is available on our website www.tracoe.com or on Facebook.

About TRACOE medical GmbH:

TRACOE medical GmbH, headquartered in Nieder-Olm (Rheinland-Pfalz), is one of the leading manufacturers and developers of medical devices and aids for patients with tracheotomies and larynx operations. Their premium product portfolio focusses on tracheostomy tubes for patient care in both hospital settings as well as at home. TRACOE medical GmbH has approximately 209 employees, incl. 17 sales representatives, exporting its products to 86 countries. In the past ten years alone, TRACOE medical has been granted 19 patents. The company can look back on a 60-year company history; it has been selected three times as one of the TOP 100 companies among German small- to medium-sized businesses and is already being led by the family's third generation. The Managing Directors are Stephan Köhler and Dr. Thomas Jurisch.

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Other information

Deutscher Pressestern®
Bierstadter Straße 9 a
65189 Wiesbaden, Germany
www.deutscher-pressestern.de

Caroline Wittemann
E-Mail: c.wittemann@public-star.de
tel. +49 611 39539-22