Medtech industry calling for MDR emergency plan

Berlin. The German medtech industry is calling for a harmonized EU-wide emergency plan. The plan must make provisions for, among other things, special approvals for manufacturers that can demonstrate their “orphaned” status – i.e., they currently have no contract with a Notified Body notified on the basis of the MDR – as well as for harmonized EU-wide permits for devices whose certification is currently on hold. BVMed is further calling for the publication of EU-wide guidelines as soon as possible in order to harmonize the activities of the Notified Bodies during the certification of manufacturers and medical devices. “Otherwise, we will see market distortions due to the present certification chaos,” warns BVMed CEO Dr. Marc-Pierre Möll. The background to these worries and demands is the application date of the EU Medical Device Regulation (MDR) from May 26, 2020, while its implementation is still facing several major problems. The second MDR corrigendum passed at the European level in mid-December 2019 was an important step in the right direction, but it concerned only a small number of around 450,000 affected medical devices, said Dr. Möll. “There are still many issues that need to be resolved, e.g., a shortage of Notified Bodies, capacity problems, the absence of implementing acts and guidelines.”

Read more at www.medinsight.de.

MDR: Five demands by the medtech industry

1. Under the MDR the Notified Bodies must be appointed immediately in order to ensure the MDR certification of manufacturers’ quality management systems as soon as possible.
2. The panels of experts must be appointed immediately in order to ensure the MDR certification of all the devices requiring certification.
3. The necessary implementing acts must be published as soon as possible, including the harmonized norms and common specifications.
4. We need high-quality guidelines to be published as soon as possible for the most urgent areas, e.g., the requirements for clinical evidence with regard to existing devices, or the definition of major changes as mentioned before, in order to ensure the swift and feasible MDR certification for as many devices as possible.
5. We need reliable time scales and deadlines for the processing of approval files by the Notified Bodies. Only these measures will allow the manufacturers to make binding plans.

Learn more at www.bvmed.de/mdr.

Basic data of the German medtech industry 2020

- 210,000 employees
- Every workplace in this industry secures 0.75 workplaces in other industries
- 9% of turnover invested in R&D
- 1/3 of turnover is achieved with devices younger than three years
- €32 bn medtech turnover
- €35 bn expenditures on medical devices in Germany
- €20 bn exports

The German medtech industry has a total turnover of over 30 billion euros and provides 210,000 jobs.