VDMA Position Paper

HealthTech

VDMA Position Paper on Medical Technology

Scope of Application of EN ISO 13485:2016 for Mechanical Engineering

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Legal notice

This position paper serves as a guide and provides an interpretation of the scope of EN ISO 13485:2016 for suppliers of machinery, plant and production equipment used in the manufacture of medical devices. It does not claim to be exhaustive, nor does it claim to give an exact interpretation of existing law. It is not intended to replace the study of relevant directives, laws and regulations. The particular features of the specific products as well as their different possible applications must also be considered. For this reason, there is a wide range of other conceivable constellations for the assessments and procedures mentioned in the position paper.

Does production technology for the manufacture of medical devices fall within the scope of European Regulation (EU) 2017/745 (MDR)?

The publication of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR for short) has significantly extended the obligations of all economic operators, particularly manufacturers of medical devices themselves. Reclassification and in many cases a higher classification in accordance with the new classification rules has become necessary for a large number of products, some of which have serious repercussions extending far into the supply chain. Medical devices are instruments, apparatus, tools, machines, appliances, implants, software, materials or other similar or related items, alone or in combination, which are intended by the manufacturer to be used for specific medical purposes. Machinery, plant and production equipment used for the manufacture of medical devices are not included.
However, the MDR requires medical device manufacturers to establish a comprehensive resource management system, which must include the selection and control of suppliers and their subcontractors. At the same time, authorities as well as notified bodies are required to deal more intensively with the suppliers of medical device manufacturers than was previously the case. In this respect, manufacturers can impose stricter requirements on suppliers and contractually restructure their cooperation with them. The manufacturing processes of medical devices and their validation must be included as design and manufacturing information in the technical documentation prepared by the manufacturer.

Is EN ISO 13485:2016 applicable to manufacturers of machinery and equipment for the production of medical devices?

Many manufacturers of medical devices and their direct suppliers are currently increasingly inclined to demand from their suppliers of production technology and production equipment the establishment of a quality management system for medical devices, EN ISO 13485:2016. However, machinery, plant and production equipment used for the manufacture of medical devices are not intended to be certified according to the scope of EN ISO 13485:2016. The scope of application defines that the standard serves to “demonstrate its [the] ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements”. Machinery or equipment for the production of medical devices cannot be considered “related services”.
It is also clarified that the term “regulatory requirements” includes statutes, regulations, ordinances or directives and limits the scope of the “applicable regulatory requirements” to those requirements for the quality management system and the safety or performance of the medical device.
As part of its quality policy, the manufacturer of medical devices is required to control any negative interactions affecting the quality of the medical device.

For this purpose, machinery and equipment must be subjected to systematic qualification in line with the scope of application and risk assessment. If qualification or comparable measures are carried out by a supplier, EN ISO 13485:2016 specifies the following: “When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4 (Purchasing).” If the supplier of machinery, plant or production equipment develops production processes and equipment for the manufacturer of medical devices, he is affected by this requirement and must control this influence with the help of his quality management system – certification according to DIN EN ISO 9001 can be regarded as sufficient for this task. The obligations required by DIN EN ISO 9001 to take the needs of the customer into account also conform to the formulations of EN ISO 13485:2016 (7.2 Customer-related processes).

Furthermore, among the answers and resolutions of the EK-Med ("experience exchange medicinal products”) of the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG), number 3.9 B18: Validierung von Prozessen der Produktion und der Dienstleistungserbringung (einschließlich Software) (“Validation of Production and Service Provision Processes (including Software)”), as well as the IAF Mandatory Documents (MD Series), IAF MD 9:2017 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485), inclusion of machinery and equipment for the manufacture of medical devices is not described. However, manufacturers must validate all production and service provision processes whose results cannot or are not verified by subsequent monitoring or measurement. The manufacturer must inform his suppliers of these core requirements relating to the influence of machinery, plant and production equipment in the requirements and functional specifications prior to placement of the order and have their assurance guaranteed.
The Machinery Regulation (Regulation (EU) 2023/1230) as a harmonised legal framework for the design and construction of machinery can serve as a basis.

Conclusions:

- Machinery, plant and production equipment for the manufacture of medical devices do not fall within the scope of European Regulation (EU) 2017/745 (MDR).
- EN ISO 13485:2016 is not applicable to manufacturers of machinery, plant and production equipment for the manufacture of medical devices.
- Certification according to EN ISO 9001 is typically sufficient for manufacturers of machinery, plant and production equipment for the manufacture of medical devices.
- The overall residual risk for medical devices is always borne by the manufacturer (MDR, Annex I, Chapter I, General Requirements).
  This responsibility cannot be delegated to all or part of the medical device supply chain by means of a quality management system.

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