99005015028000, 99005015028000

Medical devices

Modul	Sachverhalt
Leistungsschlüssel	99005015028000, 99005015028000
Leistungsbezeichnung I	Medical devices
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arzneimittel (005)
Verrichtungskennung	Überwachung (028)
SDG-Informationsbereich	
Lagen Portalverbund	Produkt- und Stoffzulassung (2120200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	18.10.2023

Modul	Sachverhalt
Fachlich freigegen durch	Hessian Ministry of Social Affairs and Integration
Handlungsgrundlage	• Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.) • Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.) • Act on the Implementation of Union Law Provisions on Medical Devices • Ordinance on the Establishment, Operation and Use of Medical Devices
Teaser	The purpose of a medical device is, among other things, to investigate, treat or alleviate diseases, injuries or disabilities. The range of medical devices is huge.
Volltext	The purpose of a medical device is, among other things, to investigate, treat or alleviate diseases, injuries or disabilities; Medical devices can also be used to change the anatomical structure or they are used to control conception. Compared to pharmaceuticals, they are distinguished by their physical mode of action. The range of medical devices is huge, ranging from simple plasters to surgical instruments and computer tomographs. In vitro diagnostic medical devices, which are also medical devices, are used to examine samples from the human body (e.g. blood samples) and to identify physiological or pathological conditions or to check therapeutic measures. The legal regulations on medical devices pursue the goal of ensuring a high level of safety for patients, users and, if necessary, third parties throughout Europe; In particular, the products must achieve the performance specified by the manufacturer and comply with the legal requirements. These requirements for the design, manufacture and placing on the market are regulated uniformly throughout

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	Europe in the Ordinance on Medical Devices (MDR) and the Ordinance on In Vitro Diagnostic Medical Devices (IVDR). There is a distinction from, for example, pharmaceuticals, wellness products or cosmetics. The Act on the Implementation of Union Law Provisions on Medical Devices (MPDG) replaces the Medical Devices Act (MPG) in Germany. Finally, the Ordinance on the Establishment, Operation and Application of Medical Devices (MPBetreibV) regulates the requirements for the safe operation and use of medical devices and sets out the obligations of the responsible persons. https://arbeitswelt.hessen.de/geraete-und-produktsicherheit/sicherheit-von-medizinprodukten https://arbeitswelt.hessen.de/geraete-und-produktsicherheit/sicherheit-von-medizinprodukten
Erforderliche Unterlagen	
Voraussetzungen	
Kosten	
Verfahrensablauf	The placing on the market of medical devices and IVDs is the responsibility of the manufacturer; unlike pharmaceuticals, it does not require regulatory approval. Medical devices and IVDs are divided into different risk classes, and the involvement of a so-called Notified Body (special private-law expert organisation) is envisaged for certain risk classes. Manufacturers must prove compliance with the legal requirements within the framework of a so-called conformity assessment procedure. In order to carry out a conformity assessment procedure, a clinical evaluation or performance evaluation is required.
Bearbeitungsdauer	
Frist	
weiterführende Informationen	
Hinweise	

Modul	Sachverhalt
Rechtsbehelf	
Kurztext	• Manufacturing and handling of medical devices Monitoring • The aim is to ensure a high level of safety for patients, users and, if necessary, third parties throughout Europe • In particular, the products must achieve the performance specified by the manufacturer and comply with the legal requirements • these requirements for the design, manufacture and placing on the market are uniformly regulated throughout Europe in the Medical Devices Ordinance (MDR) and the Ordinance on In Vitro Diagnostic Medical Devices (IVDR) • Responsibility: Regional Councils
Ansprechpunkt	Please contact the Hessian Regional Councils.
Zuständige Stelle	
Formulare	
Ursprungsportal	Medizinprodukte, Medical devices