99050050055000

Notification of the commercial handling of medical devices Transmission

Modul	Sachverhalt
Leistungsschlüssel	99050050055000
Leistungsbezeichnung I	Notification of the commercial handling of medical devices Transmission
Leistungsbezeichnung II	Report commercial handling of medical devices
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Medical devices , Registration of medical devices , Registration of in vitro diagnostic devices
Leistungstyp	

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Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	12.08.2022
Fachlich freigegen durch	
Handlungsgrundlage	Art. 31 VO EU 2017/745 i. in conjunction with § 97 MPDG Art. 28 VO EU 2017/746 i. in conjunction with § 97 MPDG Announcement according to § 97 paragraph 1 sentence 2 and paragraph 2 of the Medical Devices Law Implementation Act to regulate the transition period until the European database for medical devices is fully functional according to Article 33 of Regulation (EU) 2017/745 Announcement according to § 96a paragraph 3 and § 97a paragraph 1 sentence 2 and paragraph 2 of the Medical Devices Law Implementation Act to regulate the transition period until the European database for medical devices is fully functional according to Article 33 of Regulation (EU) 2017/745 and Article 30 of Regulation (EU) 2017/746 MPDG
Teaser	Report the commercial handling of medical devices.
Volltext	Report to the relevant authority if you placing medical devices on the market or making them available on the market, Reprocess medical devices exclusively for others who are to use them as intended in a sterile or low-germ state, placing on the market or making available on the market assembled systems or procedure packs using medical devices, or sterilize these or other medical devices for placing on the market. Please also indicate any subsequent changes to the information or any discontinuation of the product on the market.
Erforderliche Unterlagen	Please include the following in your ad: Your company

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	name and address the information concerning the common technological characteristics and analytes for reagents, medical devices containing reagents and calibration and control materials and, in the case of other in vitro diagnostic medical devices, the appropriate information, in the case of in vitro diagnostic medical devices as defined in Annex II to Directive 98/79/EC and in vitro diagnostic medical devices for self-testing, all information enabling the identification of those in vitro diagnostic medical devices, the analytical and, where appropriate, diagnostic performance data as defined in Annex I, Section A, No 3 to Directive 98/79/EC, the results of the performance evaluation and information on certificates, In the case of a "new in vitro diagnostic medical device", the additional statement that it is a "new in vitro diagnostic medical device" must be provided.
Voraussetzungen	The medical devices or in vitro diagnostic medical devices that you wish to place on the market in Germany have a CE marking.
Kosten	Fees are charged according to the time spent in accordance with the fee schedule for public consumer protection.
Verfahrensablauf	Report the commercial handling of medical devices electronically. Fill out a registration application on the online service. Share your data and send it online. The responsible authority will receive your notification. The responsible authority will then process your advertisement and release it into the relevant database. You will receive feedback about the release of the data.
Bearbeitungsdauer	There is no legally prescribed processing time.
Frist	Submit the notification before placing the medical devices on the market.
weiterführende Informationen	https://www.bfarm.de/DE/Medizinprodukte/_node.htm https://www.bfarm.de/DE/Medizinprodukte/_node.htm
Hinweise	Medical devices are instruments, apparatus, devices, software, implants, reagents and materials intended by

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	the manufacturer for human use and intended, alone or in combination, to fulfil one or more of the following purposes: the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, the diagnosis, monitoring, treatment, alleviation or compensation of injuries or disabilities, the investigation, replacement or modification of anatomy or of a physiological or pathological process or condition, contraception or the promotion of conception, cleaning, disinfection or sterilization of medical devices or their accessories. For CE certification, a procedure to confirm the essential requirements in accordance with the EU legal requirements for medical devices (conformity assessment procedure) must be successfully completed. Depending on the risk class of the medical device or in vitro diagnostic device, an expert body will be consulted.
Rechtsbehelf	contradiction
Kurztext	Notification required for: Placing or making available medical devices on the market, Reprocessing of medical devices for others that are used in a low-germ or sterile manner, Placing on the market or making available assembled systems or procedure packs using medical devices. Sterilization of medical devices for placing on the market. Subsequent changes to the information or discontinuation of marketing
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)