99050050055000, 99050050055000

Notification of the commercial handling of medical devices Transmission

Modul	Sachverhalt
Leistungsschlüssel	99050050055000, 99050050055000
Leistungsbezeichnung I	Notification of the commercial handling of medical devices Transmission
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Brandenburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gewerbe (050)
Verrichtungskennung	Übermittlung (055)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder

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	Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	01.12.2021
Fachlich freigegen durch	Ministry of Social Affairs, Health, Integration and Consumer Protection of the State of Brandenburg
Handlungsgrundlage	https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/__97.html https://www.bundesanzeiger.de/pub/publication/IGrRaNuJBWgwK7Giz8Y/content/IGrRaNuJBWgwK7Giz8Y/BAnz%20AT%2028.05.2021%20B6.pdf?inline=null https://www.bundesanzeiger.de/pub/publication/qOIieZMq3dnFbUZs734/content/qOIieZMq3dnFbUZs734/BAnz%20AT%2027.05.2022%20B4.pdf?inline=null https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0745 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX%3A32017R0746 https://www.gesetze-im-internet.de/mpdg/__97.html https://www.bundesanzeiger.de/pub/publication/IGrRaNuJBWgwK7Giz8Y/content/IGrRaNuJBWgwK7Giz8Y/BAnz%20AT%2028.05.2021%20B6.pdf?inline=null https://www.bundesanzeiger.de/pub/publication/qOIieZMq3dnFbUZs734/content/qOIieZMq3dnFbUZs734/BAnz%20AT%2027.05.2022%20B4.pdf?inline=null
Teaser	If you are based in Germany and place medical devices on the market or make them available on the market, you must first report this to the State Office for Occupational Safety, Consumer Protection and Health (LAVG).
Volltext	Medical devices are instruments, apparatus, devices, software, implants, reagents and materials intended for human use and intended, alone or in combination,

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	to perform one or more of the following purposes: - the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases,- the diagnosis, monitoring, treatment, alleviation or compensation of injuries or disabilities,- the examination, replacement or modification of the anatomy or of a physiological or pathological process or condition- contraception or promotion- the cleaning, disinfection or sterilization of medical devices or their accessories In vitro diagnostic medical device means a medical device which, as a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, device, software or system, individually or in combination, is intended by the manufacturer for the in vitro examination of samples derived from the human body, including blood and tissue donations, and is intended solely or principally to provide information on one or more of the following (a) physiological or pathological processes or conditions;(b) congenital physical or mental impairments;(c) predisposition to a particular health condition or disease;(d) to determine the safety and tolerability of potential consignees;(e) the likely effect of a treatment or the likely responses to it; or(f) for the definition or monitoring of therapeutic measures.Sample containers are considered to be in vitro diagnostic medical devices; If you are based in Germany and- place medical devices or in vitro diagnostic medical devices on the market or make them available on the market,- reprocess medical devices exclusively for others that are intended to be used in a low-germ or sterile manner,- place on the market or make available on the market systems or procedure packs assembled using medical devices, or- sterilize these or other medical devices for placing on the market,you must notify the LAVG of this before commencing the activity, stating your address. Before commencing activities, you as the manufacturer

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	must indicate the name and description of the medical devices concerned when displaying composite systems and procedure packs. If you, as a manufacturer, want to sterilize these or other medical devices before they are used, you must also indicate the designation before starting the activity. You must notify us immediately of any subsequent changes to the information and a cessation of placing on the market. The competent authority is the LAVG.
Erforderliche Unterlagen	Information on possible required data can be found in the instructions on the website of the DMIDS or EUDAMED.
Voraussetzungen	• For medical devices placed on the market in Germany, the bearing of a CE marking is mandatory. • The prerequisite for CE certification is the successful completion of a procedure to confirm the essential requirements in accordance with the EU legal requirements for medical devices (conformity assessment procedure). • Depending on the risk class of the medical device, the involvement of a notified body may be necessary.
Kosten	none
Verfahrensablauf	Before placing medical devices on the market or making them available on the market, display them online: - Fill out your online application in the DMIDS or EUDAMED.- Share your data and send it online.- The LAVG will be automatically informed about your ad.- The LAVG finally processes your ad and releases it in the appropriate database.- You will automatically receive feedback from the LAVG about the release of the data.
Bearbeitungsdauer	If all requirements are met, the average processing time is between 1 and 3 months.
Frist	Notification period: The notification must be made before the start of the activity.
weiterführende Informationen	- on the internal website of the BfArM information on:

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	• legal framework • Notification and reporting channels for manufacturers, clinical trials and incidents • competent authorities in Germany and notified bodies in the European Union https://www.bfarm.de/DE/Medizinprodukte/_node.htm https://www.bfarm.de/DE/Medizinprodukte/_node.htm
Hinweise	
Rechtsbehelf	
Kurztext	• Indication of the commercial handling of medical devices • Medical devices must be notified to the LAVG via the European Database for Medical Devices (EUDAMED) or via the German Medical Device Information and Database System (DMIDS) at the Federal Institute for Drugs and Medical Devices (BfArM) before they are placed on the market or made available on the market • Application required • responsible: State Office for Occupational Safety, Consumer Protection and Health (LAVG)
Ansprechpunkt	
Zuständige Stelle	State Office for Occupational Safety, Consumer Protection and Health (LAVG) Department of Health, Department G4
Formulare	The registration of manufacturers, importers and authorised representatives of products that comply with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 or that fall under the transitional provisions of Article 120(3) of Regulation (EU) 2017/745 or Article 110(3) of Regulation (EU) 2017/746 is carried out via EUDAMED (Actor Registration) (see point II of the BMG's announcement of 26.05.2021). The registration of devices that comply with Regulation (EU) 2017/745, as well as systems and treatment units, is carried out in accordance with Section 96 (1) MPDG via the DMIDS at the BfArM (see also point I of the BMG's announcement of 26.05.2021).

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	The registration of products that comply with Regulation (EU) 2017/746 is carried out in accordance with § 96a paragraph 1 MPDG via the DMIDS at the BfArM (see also point I of the BMG's announcement of 16.05.2022). The registration of establishments and facilities that reprocess devices that are intended to be low-germ or sterile exclusively for others, or healthcare facilities that reprocess or have reprocessed single-use devices in accordance with Article 17 (3) of Regulation (EU) 2017/745, is carried out in accordance with § 4 (1) MPDG via the DMIDS at the BfArM. https://webgate.ec.europa.eu/cas/login?loginRequestId=ECAS_LR-10656792-OyZjKbiIVtB5aXvWg442HptpXnT0U9dVrFsi2TlISlsiYuUQjucGgwgkSkaLMDx7WlyTxzV46LrdGjzlTuRH0S-jpJZscgsw0KAII5y2LJWFS-2ZhdS4UifzzuQP1wW3b03rxUat3HqQV1iVv5tKc0AkOSzJhEO9tFFVR52GesLURIYlPPiub3ue9WoHACQmCpQNm https://www.bfarm.de/DE/Medizinprodukte/Portale/DMIDS/_node.html https://webgate.ec.europa.eu/cas/login?loginRequestId=ECAS_LR-10656792-OyZjKbiIVtB5aXvWg442HptpXnT0U9dVrFsi2TlISlsiYuUQjucGgwgkSkaLMDx7WlyTxzV46LrdGjzlTuRH0S-jpJZscgsw0KAII5y2LJWFS-2ZhdS4UifzzuQP1wW3b03rxUat3HqQV1iVv5tKc0AkOSzJhEO9tFFVR52GesLURIYlPPiub3ue9WoHACQmCpQNm https://www.bfarm.de/DE/Medizinprodukte/Portale/DMIDS/_node.html
Ursprungsportal	Anzeige des gewerblichen Umgangs mit Medizinprodukten Übermittlung, Notification of the commercial handling of medical devices Transmission