99050050055000, 99050050055000

Register as an economic operator of medical devices and/or in vitro diagnostic medical devices

Modul	Sachverhalt
Leistungsschlüssel	99050050055000, 99050050055000
Leistungsbezeichnung I	Register as an economic operator of medical devices and/or in vitro diagnostic medical devices
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Schleswig-Holstein
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gewerbe (050)
Verrichtungskennung	Übermittlung (055)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder

Modul	Sachverhalt
	Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	12.10.2023
Fachlich freigegen durch	Ministry of Justice and Health of the State of Schleswig-Holstein
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpg/BJNR196300994.html
Teaser	Manufacturers, authorized representatives and importers based in Germany are obliged to register in EUDAMED or DMIDS.
Volltext	Before manufacturers, authorized representatives, importers or responsible persons who have manufacturing obligations under EU law place a medical device or in vitro diagnostic medical device on the market, they must register with both EUDAMED and the German Medical Devices Information and Database System (DMIDS). For technical reasons, manufacturers of systems and treatment centers (SPPP) are required to register in the EUDAMED "Actor Module". According to the Medical Devices Implementation Act (MPDG), the following must also be registered with DMIDS • Companies and facilities that reprocess devices that are intended to be used aseptically or sterile exclusively for others, or healthcare facilities that reprocess single-use devices or have them reprocessed, unless they are obliged to register. • Establishments and facilities that manufacture class III implantable custom-made devices All persons responsible for regulatory compliance

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	(PRRC) must be registered in EUDAMED; registration of the safety officer is no longer required in DMIDS since 26.05.2022. The terms medical devices and in vitro diagnostic medical devices are defined in the legal basis for action.
Erforderliche Unterlagen	
Voraussetzungen	• They must be based in Schleswig-Holstein. • The medical devices must bear a CE marking.
Kosten	Verwaltungsgebühr: 30€ Fee Schedule 9: Fees for receiving and checking the information submitted by the economic operator for registration. https://www.gesetze-rechtsprechung.sh.juris.de/bssh/document/jlr-VwGebVSH2018rahmen/part/X
Verfahrensablauf	• You complete the registration application in EUDAMED or DMIDS. • The State Office for Social Services is automatically informed of the application, validates the data and approves the application if the assessment is positive. • When an application is submitted via EUDAMED, the economic operator is assigned a unique number, the Single Registration Number (SRN). • The notifications in DMIDS are registered automatically
Bearbeitungsdauer	1 - 2 Monat(e) If all requirements are met, the average processing time is between 1 and 2 months.
Frist	Before starting work.
weiterführende Informationen	
Hinweise	The State Office for Social Services (LAsD), Health Protection Department, is responsible for the "Safety of Medical Devices" in Schleswig-Holstein. Further information can be found on the LAsD website. Further information on the notification obligations of

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	economic operators under MDR, IVDR and the MPDG in the DMIDS and EUDAMED systems can be found on the website of the Federal Institute for Drugs and Medical Devices under "Europe and EUDAMED". https://www.schleswig-holstein.de/DE/Landesregierung/LASD/Aufgaben/Medizinprodukteueberwachung/MedizinprodukteueberwachungSubmenue_kachelnTable.html https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Europa-und-EUDAMED/_node.html https://www.schleswig-holstein.de/DE/Landesregierung/LASD/Aufgaben/Medizinprodukteueberwachung/MedizinprodukteueberwachungSubmenue_kachelnTable.html https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Europa-und-EUDAMED/_node.html
Rechtsbehelf	- Contradiction
Kurztext	• Notification of commercial handling of medical devices Transmission • Registration of economic operators • First-time placing on the market of medical devices and in vitro diagnostic medical devices requires registration • Economic operators are registered both centrally in EUDAMED and in the German Medical Device Information and Database System (DMIDS) • Responsible: State Office for Social Services in Schleswig-Holstein
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Wirtschaftsakteur von Medizinprodukten und/oder In-vitro-Diagnostika registrieren, Register as an economic operator of medical devices and/or in vitro diagnostic medical devices