99050050055000, 99050050055000

Medical devices: Show commercial handling

Modul	Sachverhalt
Leistungsschlüssel	99050050055000, 99050050055000
Leistungsbezeichnung I	Medical devices: Show commercial handling
Leistungsbezeichnung II	
Typisierung	2/3a - Bund: Regelung, Land: Vollzug
Quellredaktion	Mecklenburg-Vorpommern
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 Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	06.07.2018
Fachlich freigegen durch	Ministry of Economics, Labor and Health Mecklenburg-Vorpommern
Handlungsgrundlage	https://www.gesetze-im-internet.de/mpg/BJNR196300994.html https://www.gesetze-im-internet.de/mpg/BJNR196300994.html https://www.landesrecht-mv.de/bsmv/document/jlr-MPKostVMVrahmen https://www.landesrecht-mv.de/bsmv/document/jlr-MPKostVMVrahmen
Teaser	Any person responsible within the meaning of Section 5 sentences 1 and 2 of the Medical Devices Act (MPG) who is based in Germany and places medical devices on the market for the first time must notify the competent authority of this before commencing activities, stating his or her address.
Volltext	Any person responsible within the meaning of Section 5 sentences 1 and 2 of the German Medical Devices Act (MPG) who is domiciled in Germany and places medical devices on the market for the first time must notify the competent authority, stating their address, before commencing their activities. The first placing of medical devices on the German market requires notification to the competent authority. Notifications are made centrally via an internet-based registration system at the German Institute for Medical Documentation and Information.
Erforderliche Unterlagen	Depending on the risk class of the product in question, the certificate of conformity of a notified body must be submitted.
Voraussetzungen	
Kosten	No fees are charged for the processing of a proper, complete notification . For official actions in connection with the notification, which are carried out in the

Modul	Sachverhalt
	interest of or at the instigation of the fee debtor, the cost range is EUR 60 - 2,200.
Verfahrensablauf	• Notification to the competent authority via the DIMDI • Plausibility check by the State Office for Health and Social Affairs (LAGuS), completion if necessary • Release of the notification https://www.lagus.mv-regierung.de/UeberDasLagus/Standorte/ https://www.lagus.mv-regierung.de/UeberDasLagus/Standorte/
Bearbeitungsdauer	
Frist	Before placing on the market
weiterführende Informationen	
Hinweise	At the request of a manufacturer or authorized representative, the competent authority for export issues a certificate of marketability of the medical device in Germany (Section 34 (1) of the Medical Devices Act).
Rechtsbehelf	
Kurztext	• Anyone placing medical devices on the market for the first time must notify the competent authority, stating their address, before commencing their activities. • The first placing of medical devices on the German market requires notification to the competent authority. • Notifications are made centrally via an internet-based registration system at the German Institute for Medical Documentation and Information.
Ansprechpunkt	
Zuständige Stelle	State Office for Health and Social Affairs (LAGuS) Mecklenburg-Western Pomerania
Formulare	
Ursprungsportal	Medizinprodukte: Gewerblichen Umgang anzeigen, Medical devices: Show commercial handling