99050178012000

Modul	Sachverhalt
Leistungsschlüssel	99050178012000
Leistungsbezeichnung I	
Leistungsbezeichnung II	
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Export certificate , certification , MDR , Export certificates for medical devices , Marketability of medical devices , Export of medical products , FSC , Free Sales Certificate , Free Sale Certificate , Certificate § 10 MPDG , apostille , legalization , <div

Modul	Sachverhalt
	lang="en-x-mtfrom-de">IVDR
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	21.07.2023
Fachlich freigegen durch	
Handlungsgrundlage	• § 10 Medical Devices Law Implementation Act • Article 60 Regulation (EU) 2017/745 (MDR) • Article 55 Regulation (EU) 2017/746 (MDR)
Teaser	
Volltext	
Erforderliche Unterlagen	• Declaration of Conformity(s) • Certificate(s) from the notified body(s) • product list
Voraussetzungen	• The product must be placed on the market according to Article 5 and Article 10 of Regulation (EU) 2017/745 for a medical device or Article 5 and Article 10 of Regulation (EU) 2017/746 for an in-vitro diagnostic device • Only manufacturers and authorized representatives based in Hamburg can apply for a free sale certificate for medical devices or in-vitro diagnostics here
Kosten	
Verfahrensablauf	1. You submit your application 2. The competent authority checks the documents 3. The competent authority may request additional documents 4. The competent authority issues the certificate

Modul	Sachverhalt
Bearbeitungsdauer	
Frist	
weiterführende Informationen	
Hinweise	
Rechtsbehelf	
Kurztext	• Free sale certificates are only issued for medical devices and in-vitro diagnostics. • A free sale certificate can only be applied for by the manufacturer or the European authorized representative based in the Federal Republic of Germany. • The medical devices and in-vitro diagnostics applied for must meet the legal requirements and be CE marked. • Within the EU and the associated contracting states, CE-marked medical products can be marketed without official confirmation. Ie no free sale certificate will be issued. • Paid service
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	Behördenfinder Hamburg, Authority finder Hamburg (Currently this link is only available in german)