99050178012004, 99050178012004

# Applying for certificates of free sale for non-active in-vitro diagnostics



| Modul | Sachverhalt |
|---|---|
| **Leistungsschlüssel** | 99050178012004, 99050178012004 |
| **Leistungsbezeichnung I** | Applying for certificates of free sale for non-active in-vitro diagnostics |
| **Leistungsbezeichnung II** | |
| **Typisierung** | 3 - Bundesaufsichtsverwaltung: Regelung |
| **Quellredaktion** | Hessen |
| **Freigabestatus Katalog** | unbestimmter Freigabestatus |
| **Freigabestatus Bibliothek** | fachlich freigegeben (silber) |
| **Begriffe im Kontext** | |
| **Leistungstyp** | Leistungsobjekt mit Verrichtung |
| **Leistungsgruppierung** | Gewerbe (050) |
| **Verrichtungskennung** | Ausstellung (012) |
| **SDG-Informationsbereich** | Feststellung der geltenden Normen, technischen Spezifikationen und Zertifizierung der Produkte |
| **Lagen Portalverbund** | Erlaubnisse und Genehmigungen (2010400), Import und Export (2070200) |

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| **Einheitlicher Ansprechpartner** | Ja |
| **Fachlich freigegeben am** | 08.02.2023 |
| **Fachlich freigegen durch** | Hessian Ministry for Social Affairs and Integration (HMSI) |
| **Handlungsgrundlage** | • Medical Devices Implementation Act (MPDG)<br>• Article 55 In-vitro Diagnostics Regulation (IVDR) - Regulation (EU) 2017/746<br>• Regulation (EU) 2017/746 Article 11 for EU authorized representatives<br>https://www.gesetze-im-internet.de/mpdg/<br>https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746<br>https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746<br>https://www.gesetze-im-internet.de/mpdg/<br>https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32017R0746<br>https://eur-lex.europa.eu/legal-content/de/ALL/?uri=CELEX%3A32017R0746 |
| **Teaser** | Are you responsible for placing an in-vitro diagnostic product on the market and would like to export it outside the Union? Then the relevant competent authority will issue a certificate upon your request. |
| **Volltext** | Are you responsible for placing an in vitro diagnostic medical device on the market in accordance with Article 5 and Article 10 of Regulation (EU) 2017/746 and would like to export it outside the Union? Then the relevant competent authority will issue a certificate in accordance with Section 10 MPDG at your request.<br><br>This certificate certifies that the product may be traded in the Union. |
| **Erforderliche Unterlagen** | • Declaration of conformity<br>• Certificate(s) of the Notified Body(ies)<br>• Product list |
| **Voraussetzungen** | • Product must be placed on the market in accordance with Article 5 Article 10 of Regulation (EU) 2017/746 of an in vitro diagnostic medical device |

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| | • Only manufacturers and authorized representatives based in Germany can submit an application for a certificate of free sale for in vitro diagnostic medical devices here |
| **Kosten** | Cost type: variable<br><br>Description of costs: Fee<br><br>Note: Medical device law is federal law and enforcement is the responsibility of the respective federal states. Therefore, the respective cost or fee regulations of the federal state must be applied. |
| **Verfahrensablauf** | 1. You submit your application<br>2. The competent authority checks the documents<br>3. The competent authority requests additional documents if necessary<br>4. The competent authority issues the certificate |
| **Bearbeitungsdauer** | 1 - 3 Woche(n)<br>Duration: 1 to 3 |
| **Frist** | The certificate of marketability according to § 10 MPDG does not contain any time limits. It confirms the status as of the date of issue. Each recipient country decides on the period of validity of the certificate itself. |
| **weiterführende Informationen** | |
| **Hinweise** | |
| **Rechtsbehelf** | Objection under the VwVfG against the rejection of an application and the charging of fees |
| **Kurztext** | • Certificates of free sale for export purposes for medical devices Exhibition For in vitro diagnostics - not active<br>• Certificates of free sale are issued exclusively for medical devices and in vitro diagnostics.<br>• A certificate of free sale can only be applied for by the manufacturer or the European authorized representative based in the Federal Republic of Germany.<br>• The medical devices and in vitro diagnostic medical |

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| | devices applied for must meet the legal requirements and be CE-marked.<br>• CE-marked medical devices and in-vitro diagnostics can be marketed within the EU and the associated contracting states without official confirmation. This means that no certificate of free sale is issued.<br>• Fee-based service |
| **Ansprechpunkt** | Please contact the Regierungspräsidium Kassel. |
| **Zuständige Stelle** | Regional Council Kassel |
| **Formulare** | Forms available: No Written form required: No Informal application possible: Yes Personal appearance necessary: No |
| **Ursprungsportal** | Freiverkaufszertifikate für nicht-aktive In-vitro Diagnostika beantragen, Applying for certificates of free sale for non-active in-vitro diagnostics |