99050050000000, 99050050000000

# Notification of the commercial handling of medical devices



| Modul | Sachverhalt |
|---|---|
| **Leistungsschlüssel** | 99050050000000, 99050050000000 |
| **Leistungsbezeichnung I** | Notification of the commercial handling of medical devices |
| **Leistungsbezeichnung II** | |
| **Typisierung** | 2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug |
| **Quellredaktion** | Niedersachsen |
| **Freigabestatus Katalog** | unbestimmter Freigabestatus |
| **Freigabestatus Bibliothek** | unbestimmter Freigabestatus |
| **Begriffe im Kontext** | |
| **Leistungstyp** | |
| **Leistungsgruppierung** | |
| **Verrichtungskennung** | |
| **SDG-Informationsbereich** | |
| **Lagen Portalverbund** | Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400) |

| Modul | Sachverhalt |
| --- | --- |
| **Einheitlicher Ansprechpartner** | Nein |
| **Fachlich freigegeben am** | 19.11.2009 |
| **Fachlich freigegen durch** | |
| **Handlungsgrundlage** | https://www.gesetze-im-internet.de/mpg/BJNR196300994.html<br>https://www.gesetze-im-internet.de/mpg/BJNR196300994.html |
| **Teaser** | |
| **Volltext** | If you<br><br>• place medical devices or in vitro diagnostic medical devices on the market for the first time,<br>• process medical devices that are used as intended to be low-germ or sterile exclusively for others,<br>• Assembling or sterilizing systems or dental units as well as medical devices<br><br>you must notify the competent authority of this. |
| **Erforderliche Unterlagen** | • the appropriate information on reagents, medical devices with reagents and calibrators and control materials relating to common technological characteristics and analytes, and for other in vitro diagnostic medical devices;<br>• in the case of in vitro diagnostic medical devices listed in Annex II to Directive 98/79/EC and in vitro diagnostic medical devices for self-testing, all information enabling those in vitro diagnostic medical devices to be identified, the analytical and, where applicable, diagnostic performance data referred to in point 3 of Section A of Annex I to Directive 98/79/EC, the results of the performance evaluation and information on certificates;<br>• in the case of a "new in vitro diagnostic medical device" within the meaning of the word, an additional indication that it is a "new in vitro diagnostic medical device" |
| **Voraussetzungen** | |

| Modul | Sachverhalt |
| --- | --- |
| **Kosten** | Fees may apply. Please contact the relevant authority. |
| **Verfahrensablauf** | |
| **Bearbeitungsdauer** | |
| **Frist** | The notification must be made before the start of the activity. |
| **weiterführende Informationen** | |
| **Hinweise** | |
| **Rechtsbehelf** | |
| **Kurztext** | |
| **Ansprechpunkt** | The responsibility lies with the Federal Institute for Drugs and Medical Devices. http://www.bfarm.de/cln_103/DE/Home/home_node.html http://www.bfarm.de/cln_103/DE/Home/home_node.html |
| **Zuständige Stelle** | |
| **Formulare** | |
| **Ursprungsportal** | Anzeige des gewerblichen Umgangs mit Medizinprodukten, Notification of the commercial handling of medical devices |