

Identification of GMDN Level 2 Categories: Guidance for Manufacturers

Disclaimer:

The guidance provided by the GMDN Agency has been prepared in good faith and is intended to offer general information and assistance. However, it is important to note that any guidance or directives issued by the [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#) take precedence over this document.

The MHRA will introduce a new annual medical devices registration fee to support post-market surveillance (PMS), effective from **1 April 2026**, based on **GMDN Level 2 Categories** (or Level 1, where no Level 2 exists).

All fees paid go solely to the [MHRA](#).

Key Actions for Manufacturers

- **Ensure accurate GMDN Term selection**
Assigning the correct GMDN Term to each of your devices remains critical. We recommend incorporating a regular review of GMDN Term assignments into your quality processes to ensure accuracy and compliance.
- **Recognise the wider impact of GMDN data**
GMDN data is increasingly used by stakeholders across the NHS and beyond, particularly for procurement purposes. Inaccurate assignment may not only affect compliance but could also result in lost opportunities.

Understanding GMDN Categories

Each GMDN Term is mapped to several Categories, grouped under different headers. The MHRA's new annual medical devices registration fee will use the **Device Function** header to calculate the charge.

- Under **Device Function**, there are **22 Level 1 Categories**
- Each Level 1 Category contains multiple **Level 2 Categories**
- Some GMDN Terms are only linked at **Level 1**
- Some GMDN Terms may be associated with **multiple Device Function Categories** at either **Level 1 or Level 2**.

The [MHRA](#) will advise on how these cases are to be managed.

How to find your GMDN Term Level 2 Category data

- If you have a **Manufacturer GMDN membership account**, then the easiest way to find the Level 2 Category data is via your **My Terms** section of your account.

- Logon to the GMDN Database using your Username and Password. The **My Terms** page is found in the dropdown list in the **Terms** menu at the top of the webpage.
- By clicking on **My Terms** the list of purchased GMDN Terms is displayed for your account.
- Click on the **Details** link and you can see more information relating to that GMDN Term.
- On each '**Terms Details**' page at the bottom is a list of all Categories linked to that GMDN Term. You can then see what **Level 2 Category** your GMDN Term is under the **Device Function** header. (example below)

GMDN Home Terms Help manufacturer

Term Details

You purchased this term on 04 Sep 2024. [My Terms](#)

Name Drug-eluting coronary artery stent, fully-bioabsorbable

Definition A bioabsorbable tubular or coil-shaped device with a drug coating intended to be implanted, via a delivery catheter, into a de novo or restenotic native coronary artery during a percutaneous coronary intervention (PCI) to temporarily maintain its patency, typically in patients with symptomatic atherosclerotic heart disease. The drug is intended to release slowly to inhibit restenosis by reducing vessel smooth muscle cell proliferation. The device is made of a material capable of being degraded and absorbed by body tissues (e.g., bioabsorbable polymer) and is designed to remain in the vessel to provide support for the stenosed lesion until it degrades.

Code 56304

Term Status Active

Created Date 28 Apr 2010

Modified Date 12 Apr 2024

Reason for modification/obsolescence The definition of this term has only been slightly edited to better define drug-eluting function; the scope of the term has not changed.

[Get Code](#) [Add to My Shortlist](#) [Add to Custom Category](#) [Move to My Archive](#) [Return to My Terms](#)

Note: Terms in "My Archive" do not generate Alerts.

Translations

Language

Categories

Please use shortcuts to find related Terms

Anatomical Specialty / Cardiovascular devices / Vascular stents / Bioabsorbable vascular stents

Anatomical Specialty / Cardiovascular devices / Vascular stents / Coronary artery stents / Drug-eluting coronary artery stents

Anatomical Specialty / Cardiovascular devices / Vascular stents / Drug-eluting vascular stents / Drug-eluting coronary artery stents

Device Function / Tissue repair devices / Stents / Bioabsorbable stents / Bioabsorbable vascular stents

Device Function / Tissue repair devices / Stents / Vascular stents / Bioabsorbable vascular stents

Device Function / Tissue repair devices / Stents / Vascular stents / Coronary artery stents / Drug-eluting coronary artery stents

Please note that if you have a Basic GMDN membership account, then the Category data is not available under that membership type.

Further support

We also have GMDN user guides and videos on our Training page that can be viewed [here](#). These will help you to maximise your use of the GMDN Database. You can also contact us via this [link](#) with any other queries.

*NEW SERVICE COMING FOR GMDN MANUFACTURER MEMBERS *

Week commencing 22nd September 2025, we will be contacting GMDN members with a [Manufacturers Membership](#), providing details on our new service to identify GMDN Level 2 Categories.

Please note: This new GMDN service is for "[Manufacturer Members](#)" only.

