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### 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 <a href="the Medicines and Healthcare products">the Medicines and Healthcare products</a> Regulatory Agency (MHRA) take precedence over this document.

# Identification of GMDN Level 2 Categories: A GMDN service for "Manufacturer Members" only

**Starting the first week of October 2025**, GMDN members with a **Manufacturers membership** will be able to:

- Submit a list of GMDN Term Codes associated with their devices to the GMDN Agency, for which they want to know the Device Function Category details.
- The GMDN Agency will then return the corresponding **Device Function Category Codes and Names** either **Level 2 (L2)** or **Level 1 (L1)** for each **GMDN Term**This service will support improved classification, regulatory alignment, and data consistency across the UK medical device landscape.

# <u>Submission Guidelines (Effective October 2025)</u>

Medical device manufacturers should submit their **GMDN Term Codes** to the GMDN Agency as follows:

- Only one file per company account to be sent
- File Format: Excel spreadsheet (.xlsx)
- File Name Format: GMDN member number\_GMDNCodes\_dd-mm-yyyy.xlsx

Example - B99999\_GMDNCodes\_01-10-2025.xlsx

- Replace **B99999** with your GMDN member account number you can find this on your <u>GMDN account profile</u>
- Worksheet Name: GMDN member number\_GMDNCodes

e.g. B99999\_GMDNCodes (Fig.1)

- Content:
- One column containing GMDN Term Codes only
- Please remove any duplicates
- Active GMDN Terms only (If you have any obsolete GMDN Terms you will need to reassign to an alternative GMDN Term. Guidance on how to do that is found <a href="https://doi.org/10.2016/need/">here</a>)

Send your file to: <u>orders@gmdnagency.org</u> please include your file name in the subject header

The GMDN Agency will return the corresponding **Device Function Category Codes and Names** (Level 2 or Level 1) for each valid GMDN Term.

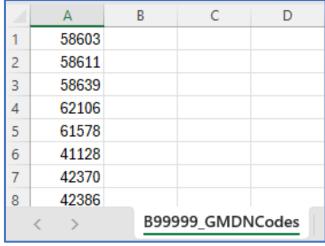


Fig.1

### **Important notes**

GMDN Agency will only work on the "Active" GMDN Terms list you provide; therefore, we strongly advise all to ensure accurate GMDN Term selection is finalised before you send to the GMDN Agency.

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.

The GMDN Agency will then return the same spreadsheet with an additional worksheet: **GMDN\_DFCatL1&2** (Fig.2)

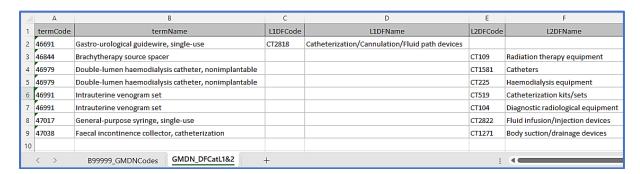


Fig.2

### <u>Understanding Device Function Category Assignments</u>

When submitting your GMDN Term Codes, please note the following:

- If a Level 2 (L2) Device Function Category exists for a Term, it will be provided.
- If no L2 Category is available, the **Level 1 (L1)** Category will be shown, and the L2 field will be blank.

### **Multiple Category Assignments**

Some GMDN Terms may be associated with **multiple Device Function Categories** at either L1 or L2.

The MHRA will advise on how these cases are to be managed.

## **Guidance and Support**

For the most current and authoritative advice on handling multiple Category assignments, please refer directly to the MHRA.

## **My Categories**

Manufacturers can also use the 'My Categories' function we launched last year. This function allows you to add specific GMDN Categories to your account that are of interest to you or your organisation.

The user of the GMDN account with the appropriate account permission can add, modify, and delete My Categories associated with their membership account.

Details on how to use 'My Categories' can be found in the GMDN User Guide for Manufacturers on this page.