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GMDN ENQUIRY PROCESS TERMS
(last updated: 21 February 2025)

Our Enquiry Form can be used to access assistance from the GMDN Agency in relation to:

- the identification of the appropriate GMDN Term to be used for a particular medical device;
- assess whether a definition of an existing Term needs to be modified for the device in question; or
- assess whether a new GMDN Term needs to be created to include your product variant.

The Term Development Team will assess your Enquiry and decide which is the most appropriate approach for your Enquiry.

Separate Enquiries must be submitted for products unrelated to each other.

Process

Please complete the Form in as much detail as you can and ensure the information you provide is accurate and complete. Please note charges may apply to the submission of the Enquiry Form – see below for details. If you provide incomplete or inaccurate information, the GMDN Agency reserves its rights to require the submission of additional supporting documents.

Once we receive your Enquiry, we will allocate to the most appropriate expert in our team for review. We have an ISO 9001 Quality Management Procedure to control and document our service, so you can be assured your data is secure.

Our expert will review your Enquiry and may request further information from you, using the contact details you provide.

As part of our commitment to provide an accurate nomenclature, we may in some circumstances, engage with relevant Regulators to seek their perspective on the most effective categorisation of certain devices. In such rare circumstances, we will limit the details provided to Regulators to a description of the relevant device on a 'no names' basis, and we will not share the details of you or your organisation or brands.

At the end of the Enquiry process, we will send you draft Term(s) and an opportunity to provide feedback.

When you submit the Enquiry Form, you acknowledge and agree that:

- You are authorised to complete and submit the Form on behalf of your organisation;

- The information contained on the Enquiry Form is complete and correct to enable us to advise on the most appropriate Term, Term modifications or new Term;
- The GMDN Agency will be entitled to share details of the device which is the subject of the Enquiry with relevant regulators on a 'no names' basis as described above; and
- While we will consider all feedback provided, please note that any modifications to Terms or new Terms created by the GMDN Agency following the Enquiry process are at the sole discretion of the GMDN Agency.
- Suggestion of a GMDN Term, or publication of a new GMDN Term in response to an Enquiry is not intended to be and will not constitute an endorsement by the GMDN Agency of any device, or its performance, or any other claims made by the manufacturer in respect of a device. All rights (including all intellectual property rights) in all new Terms or Term modifications, and their related definitions are owned by the GMDN Agency.

Charges

Please note that the following charges apply in respect of Enquiry submissions:

- Regulators, Healthcare Providers and Paid Manufacturer members receive unlimited free priority Enquiries.
- Consultancy or Commercial Organisation members receive 2 Free Enquiry Service Credits, any subsequent Enquiries are charged at £100 per submission.
- Basic members are charged £100 per Enquiry submission.
- Please visit https://www.gmdnagency.org/membership-type-comparison/ for more information.