



# Feasibility of mapping the GMDN (Global Medical Device Nomenclature) to the EMDN (European Medical Device Nomenclature)

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# Feasibility of mapping the GMDN (Global Medical Device Nomenclature) to the EMDN (European Medical Device Nomenclature)

## Abstract

Introduction: The Global Medical Device Nomenclature (GMDN) and European Medical Device Nomenclature (EMDN) are two approaches for naming and grouping medical devices. This work evaluates the feasibility of a direct term-to-term mapping of the GMDN to the EMDN. This is an attempt to support global harmonization for appropriate grouping of, and exchange of information about, medical devices across different jurisdictions for regulatory and other purposes.

Areas covered: Our study involved, for each general medical device GMDN Term, a manual comparison to all EMDN terminal terms and selecting the closest corresponding EMDN term. The GMDN Terms for which a closely corresponding specifically named EMDN term could not be found were mapped to an 'other/various' EMDN terminal term.

Expert Opinion/Commentary: The majority of the GMDN Terms corresponded to 'other/various' EMDN terminal terms. The fundamental differences in categorisation parameters between the GMDN and EMDN undermine attempts at a direct mapping. The 'other/various' EMDN terminal terms are not a useful tool to support cross-jurisdiction data analysis because they are non-homogenous concepts grouping devices with potentially different features. In our opinion, a mapping of this kind is not an effective approach to the global harmonization of medical devices.

## Keywords

GMDN, EMDN, medical device nomenclature, mapping.

## 1. Introduction

The Global Medical Device Nomenclature (GMDN) and European Medical Device Nomenclature (EMDN) are two alternative approaches for naming and grouping medical devices, including implantable devices, medical equipment, consumables, and in-vitro diagnostic (IVD) devices. The GMDN is used for product registration and information exchange (e.g., during post-market surveillance, safety, and efficacy analysis) in different countries, including USA [in the Global Unique Device Identification Database (GUDID) [1]], Canada, UK and Australia.

GMDN Terms are updated in real time based on information given by manufacturers and are published on the GMDN Agency website. Each GMDN Term consists of a unique 5-digit code (allocated sequentially), a name and a definition. The GMDN Terms are mutually exclusive (their concepts do not overlap with each other), written with a consistent and rationalised approach to

granularity, and are organized in a multi-hierarchical classification system of Categories (Figure 1) [2].

EMDN was devised for the registration of products in the European Database on Medical Devices (EUDAMED). It was substantially based on the Italian medical device classification CND (Classificazione Nazionale Dispositivi medici) [3] and is published in the form of new versions on the European Commission website. Each EMDN term consists of a code and a name, without a definition. The code is alphanumeric, allocated to the term depending on its related specialty (e.g., C for cardiocirculatory, G for gastrointestinal) and position in a single-hierarchical classification system (also known as intelligent numbering). The terminal (lowest) level terms can exist at any level of the hierarchy. The terminal level includes terms named 'other' or 'various' [in other classification systems these are known as 'not elsewhere classified' (NEC) or 'not otherwise specified' (NOS)] that are intended to group devices that are not adequately described by the rest of the available (specifically named) terms [4].

## 2. Purpose

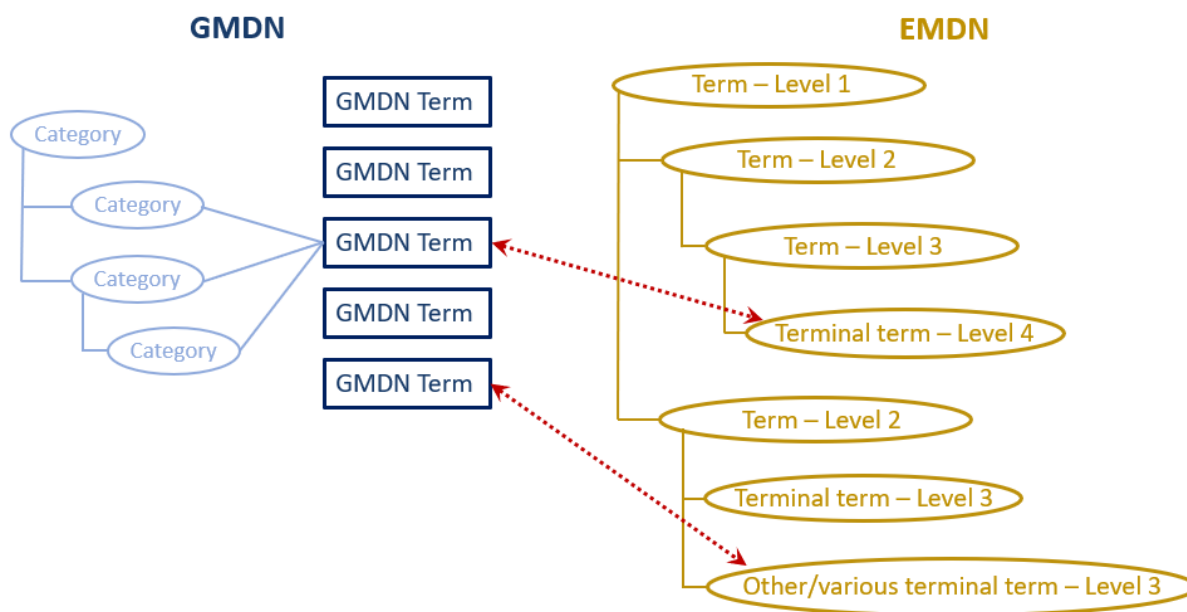
The purpose of this work is to evaluate the feasibility of a direct term-to-term mapping of the GMDN to the EMDN by finding the best correspondence of each GMDN Term to a terminal level EMDN term (Figure 1). Correspondence of the GMDN Categories to higher level EMDN terms was not tested. This is an attempt to support global harmonization for appropriate grouping of and exchange of information (e.g., for post-market surveillance, safety, effectiveness) about medical devices across different jurisdictions (e.g., between UK or USA, and EU).

The European Commission have suggested that they would provide a map between EMDN and GMDN but have not published [5]. The WHO have completed a feasibility study of using artificial intelligence/machine learning techniques for creating a map using data of alternative assignments of GMDN and EMDN to individual products in public databases; this work is not published [6]. To the best of our knowledge, this article describes the first published attempt of a large-scale direct term-to-term mapping.

## 3. Methods

**Method 1:** Our feasibility study was carried out by the GMDN Term Development Team with life science and/or clinical background/experience. It included all general medical device (non-IVD) GMDN Terms (approximately 10,000) which were published on 30 November 2021 on the GMDN Agency website [2], and all EMDN terminal-level terms (approximately 8,000) which were published in May 2021 on the European Commission website (version 1.1) [4]. It involved manual search of each general medical device GMDN Term, comparison to the EMDN terms that existed at the terminal level, and empirical finding of its closest corresponding EMDN terminal term. The closest corresponding was a specifically named EMDN terminal term with the same or similar name. The

GMDN Terms for which a close corresponding, specifically named EMDN terminal term could not be found were unavoidably mapped to an other/various named EMDN terminal term (Figure 1).



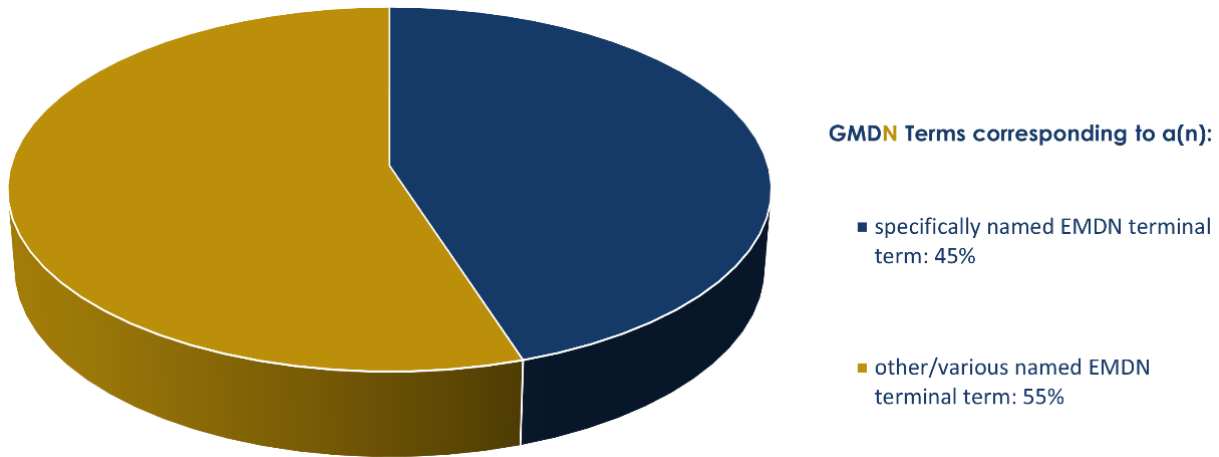
**Figure 1.** Diagram showing the GMDN in comparison with the EMDN hierarchical structure. The GMDN Terms are organized in a multi-hierarchical classification system of Categories (they belong in Categories of more than one branch of the hierarchy). The EMDN has a single-hierarchical structure. Mapping method 1 involves finding best correspondence between each GMDN Term and an EMDN terminal (lowest) level term as shown by the dotted arrows.

**Method 2:** An alternative approach was trialled for feasibility, whereby the separate assignments of GMDN and EMDN to individual products in public databases was compared for each product. Preliminary results produced a many-to-many relationship between GMDN Terms and EMDN terminal terms consisting of close, questionable, or incorrect matches. This approach did not provide a better direct term-to-term correspondence and could not be carried out in a shorter timescale, than the manual approach (method 1) we adopted.

#### 4. Results and Discussion

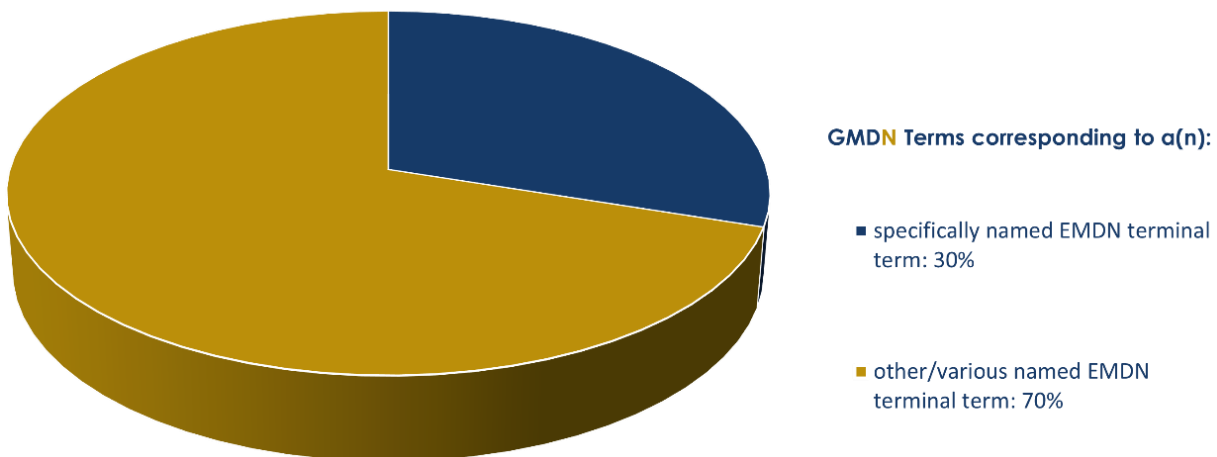
The results of the direct term-to-term correspondence (method 1) are summarised in the pie charts below. Each pie chart groups the GMDN Terms based on a common GMDN attribute. The definition of each attribute is mentioned in the caption of the respective pie chart.

## GMDN Terms in GUDID with >20,000 assigned devices (33 terms)



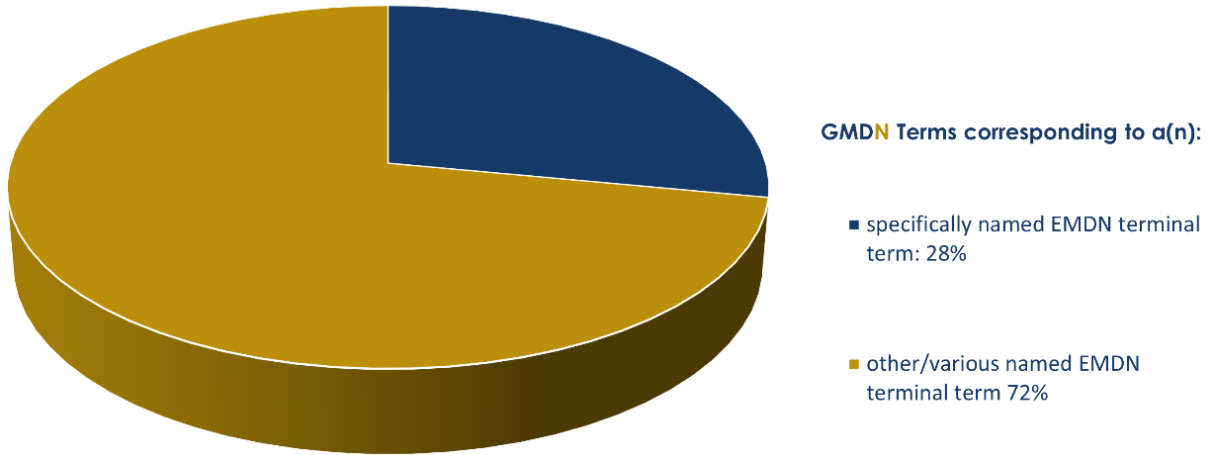
**Pie chart 1.** Correspondence of the GMDN Terms and EMDN terminal terms, for the GMDN Terms that have over 20,000 assigned devices in the GUDID [1]. This is focused on the most highly used GMDN Terms.

## Transient Surgical Invasive GMDN Terms (2,153 terms)



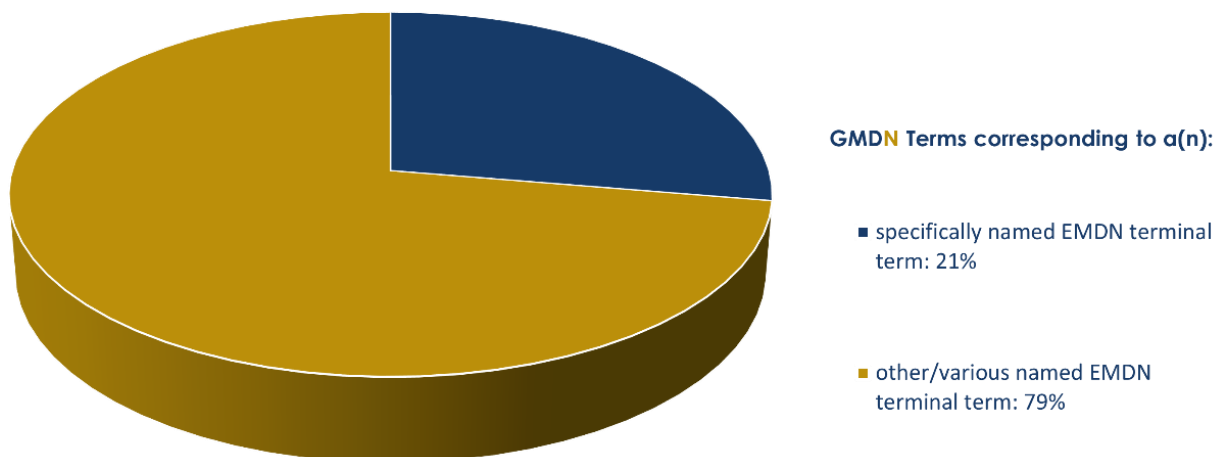
**Pie chart 2.** Correspondence of the GMDN Terms and EMDN terminal terms describing transient surgical invasive devices (introduced into the body involving physical penetration of tissues and remaining there for a period of less than 24 hours)

### Short-Term Surgical Invasive GMDN Terms (262 terms)



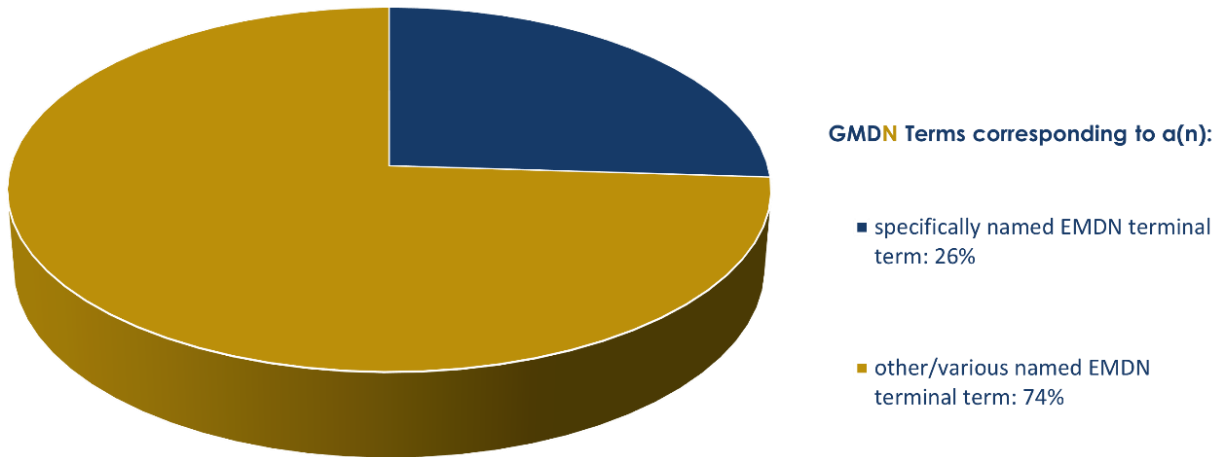
**Pie chart 3.** Correspondence of the GMDN Terms and EMDN terminal terms describing short-term surgical invasive devices (introduced into the body involving physical penetration of tissues and remaining there for a period of 1 to 30 days).

### Long-Term Surgical Invasive GMDN Terms (970 terms)



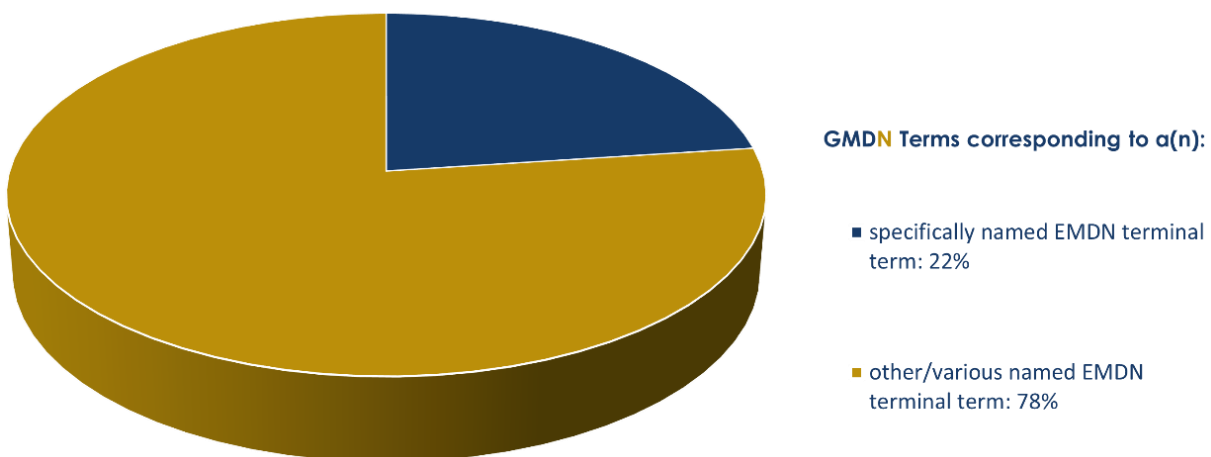
**Pie chart 4.** Correspondence of the GMDN Terms and EMDN terminal terms describing long-term surgical invasive devices (introduced into the body involving physical penetration of tissues and remaining there for a period of more than 30 days - these devices are implantable).

## Active Implantable GMDN Terms (78 terms)



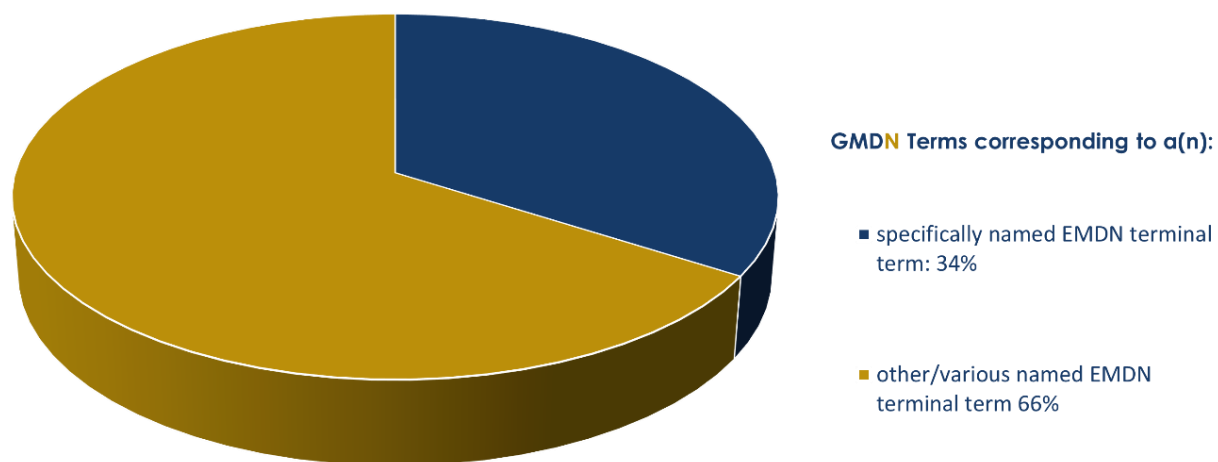
**Pie chart 5.** Correspondence of the GMDN Terms and EMDN terminal terms describing active implantable devices [function dependent upon an energy source, apart from human body energy or gravity, intended to be totally or partially introduced into the human body or body-orifice (surgically or medically) and remain for longer than 30 days].

## Non-Active Implantable GMDN Terms (942 terms)



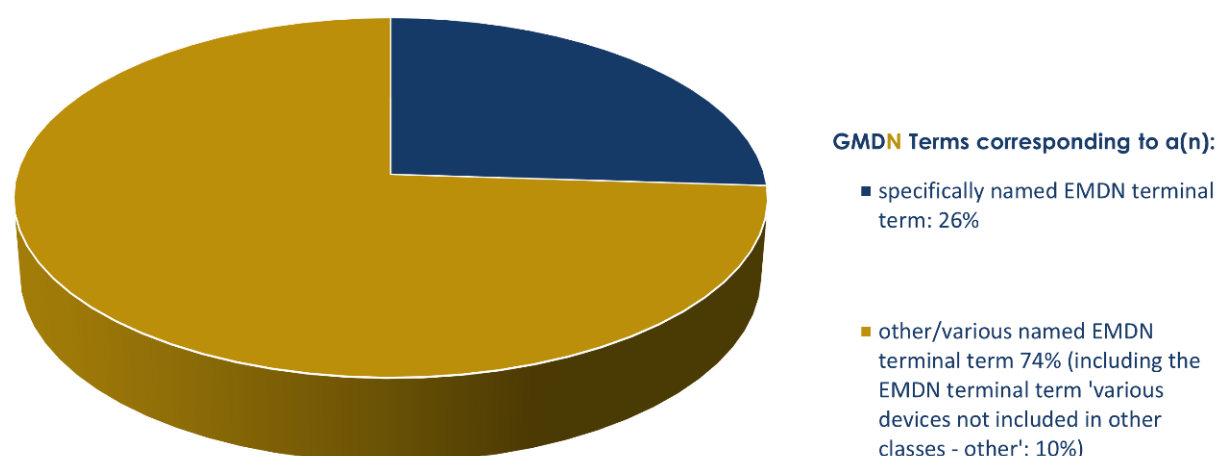
**Pie chart 6.** Correspondence of the GMDN Terms and EMDN terminal terms describing non-active implantable devices [function independent of an energy source, apart from human body energy or gravity, intended to be totally or partially introduced into the human body or body-orifice (surgically or medically) and remain for longer than 30 days].

## Cardiovascular GMDN Terms (1,088 terms)



**Pie chart 7.** Correspondence of the GMDN Terms and EMDN terminal terms describing cardiovascular devices (fully or substantially dedicated to the measurement or monitoring of physical and functional cardiovascular parameters, or to the treatment and management of diseases/disorders of the heart and blood vessels).

## Total General Medical Device GMDN Terms (10,783 terms)



**Pie chart 8.** Correspondence of the GMDN Terms and EMDN terminal terms describing all the general medical devices (non-IVD), including correspondence to the EMDN terminal term 'Various devices not included in other classes – other'.



The above pie charts show a low level of correspondence between the GMDN Terms and EMDN terminal terms. The correspondence to a specifically named EMDN terminal term for each attribute ranged from 21% (Long-term surgical invasive GMDN Terms, Pie chart 4) to 34% (Cardiovascular GMDN Terms, Pie chart 7), with only 26% of the total general GMDN Terms used in this work corresponding to a specifically named EMDN terminal term (Pie chart 8). In addition, 10% of the total general medical device GMDN Terms corresponded to the EMDN terminal term ‘Various devices not included in other classes – other’ (Pie chart 8).

This term does not have a specific device concept, potentially grouping completely different devices. As an example, the quite disparate GMDN Terms ‘Fluorescent-hydrogel subcutaneous oxygen sensor’ and ‘Pyelovesical shunt’ both show best correspondence to this EMDN terminal term ‘Various devices not included in other classes – other’.

The low accuracy of the correspondence was expected because of the different attributes used between GMDN Terms and EMDN terminal terms for grouping the same device concepts. Examples of the GMDN-to-EMDN mismatches are shown in the ‘widget’ terms (non-existing concept shown only for illustration purposes) below (Table 1) and breast implant terms (Table 2).

The ‘widget’ terms have different attributes between the GMDN Terms (material-based) and EMDN terminal terms (shaped-based), and the GMDN Terms would correspond to the ‘other’ EMDN terminal term. For the breast implants, it was noticed that the hierarchy of GMDN was different to that of CND (Table 2a) [7]. Subsequently the EMDN terminal terms were updated with attributes corresponding to the GMDN Terms (saline or silicone; smooth- or textured-surface) (Table 2b).

Direct term-to-term correspondence however could still not be achieved because the EMDN higher level attributes ‘round’ and ‘anatomical’ remained, and do not exist in GMDN. The GMDN Terms were therefore unavoidably mapped to the ‘other’ EMDN terminal terms.

An update to a classification based on an intelligent numbering/coding, that involves introducing a new attribute distinction in the middle of the hierarchy, requires obsolescence and replacement of every term at, and below, the level of the change.

1.

<b>GMDN</b>	<b>EMDN</b>
Widget, metal	Widget, round
Widget, polymer	Widget, square
Widget, ceramic	Widget, <b>other</b>

## 2a.

GMDN	CND
Breast implants:	P06 Breast prostheses:
<b>Saline</b> -filled breast implant, unstructured, <b>smooth-surface</b>	P0601 Breast prostheses, standard
<b>Saline</b> -filled breast implant, unstructured, <b>textured-surface</b>	P060101 Breast prostheses, round
<b>Saline</b> -filled breast implant, internally-structured	P060102 Breast prostheses, anatomic
<b>Silicone</b> gel-filled breast implant, <b>smooth-surface</b>	P060199 Breast prostheses - <b>others</b>
<b>Silicone</b> gel-filled breast implant, <b>textured-surface</b>	
<b>Silicone</b> gel/ <b>saline</b> -filled breast implant	

## 2b.

EMDN
P06 Breast prostheses:
P060101 Breast prostheses, round
P06010101 Breast implants, round, <b>saline</b>
P0601010101 Breast implants, round, <b>saline</b> , <b>smooth surface</b>
P0601010102 Breast implants, round, <b>saline</b> , <b>textured surface</b>
P0601010199 Breast implants, round, <b>saline</b> - <b>other</b>
P06010102 Breast implants, round, <b>made of silicone</b>
P0601010201 Breast implants, round, <b>made of silicone</b> , <b>smooth surface</b>
P0601010202 Breast implants, round, <b>made of silicone</b> , <b>textured surface</b>
P0601010299 Breast implants, round, <b>made of silicone</b> - <b>other</b>
P060102 Breast implants, anatomic
P06010201 Breast implants, anatomical, <b>saline</b>
P0601020101 Breast implants, anatomical, <b>saline</b> , <b>smooth surface</b>
P0601020102 Breast implants, anatomical, <b>saline</b> , <b>textured surface</b>
P0601020199 Breast implants, anatomical, <b>saline</b> - <b>other</b>
P06010202 Breast implants, anatomical, <b>made of silicone</b>
P0601020201 Breast implants, anatomical, <b>made of silicone</b> , <b>smooth surface</b>
P0601020202 Breast implants, anatomical, <b>made of silicone</b> , <b>textured surface</b>
P0601020299 Breast implants, anatomical, <b>made of silicone</b> - <b>other</b>
P060199 Breast implants, standard - <b>other</b>

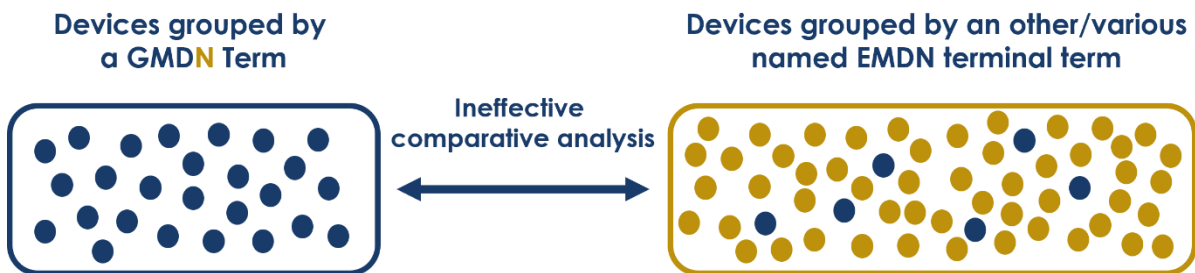
**Tables 1, 2.** Examples of GMDN Term-to-EMDN terminal term mismatches for the (1) widgets (non-existing term concept shown for illustration purposes) and (2) breast implants. For the breast implants, the EMDN terminal level terms were updated from CND to attributes corresponding to the GMDN Terms (highlighted in green/gold/red/purple). For both name concepts, the GMDN Terms corresponded to 'other' EMDN terminal terms (in grey).

## 5. Conclusion

There are inherent differences between the GMDN and the EMDN data design and structure. The GMDN consists of specifically named, mutually exclusive terms, while EMDN includes terminal level 'other' and 'various' terms; these are the terms that represent the variety of devices not included in specifically named terms (Figure 1). The attributes between the GMDN and EMDN are different for many device types (Tables 1 and 2). Furthermore, the EMDN terms do not have definitions. Our feasibility study shows that when mapping GMDN Terms to EMDN terminal terms based on best correspondence (method 1), the majority of the GMDN Terms unavoidably correspond to other/various named EMDN terminal terms. The fundamental differences in categorisation parameters between the GMDN and EMDN undermine attempts at a direct mapping.

## 6. Expert Opinion

Our work shows that a direct term-to-term mapping of the GMDN Terms to the EMDN terminal terms is not fit for grouping medical devices with similar features between different jurisdictions (e.g., between UK or USA, and EU). The other/various named EMDN terminal terms that were predominantly used are not suitable for a direct term-to-term correspondence, because they are broad concepts grouping devices with potentially different features (Figure 2). In our opinion, this is not an effective approach to the global harmonization of medical devices.



**Figure 2.** Diagram showing the correspondence of a GMDN Term to an other/various named EMDN terminal term. The GMDN Term covers a narrow range of devices (in blue), while the other/various named EMDN terminal term covers a potentially broader range of devices (in gold), including some of the devices covered by the GMDN Term. This does not allow for effective exchange of information based on grouping devices with similar features.

Mapping GMDN Terms and EMDN terminal terms based on common device assignment is an alternative method (discussed in method 2), comparable to that undertaken by the WHO [6]. However, this is expected to show a more complex, many-to-many correspondence which will consist of close, questionable, or incorrect matches between GMDN Terms and EMDN terminal terms. The many terms will group a broader range of devices than single terms used in a one-to-one relationship, that will very likely include devices with different features that may be irrelevant to each other, similarly to an other/various named EMDN term. Furthermore, a many-to-many term relationship will be very likely hard to maintain, as GMDN and EMDN unavoidably are changed with

time because of the evolution of medical devices. In our opinion, this also is not fit for grouping medical devices with similar features between different jurisdictions.

Adding another nomenclature or classification system with potentially different features than GMDN and EMDN [e.g., UNSPSC, Universal Medical Device Nomenclature System (UMDNS) [8]] to the existing correspondence is expected to drop the overall accuracy further. Additionally, the update of any correspondence data will be problematic because the publishing schedules between GMDN (individual terms updated in real-time) and EMDN (whole database as a new version) are not aligned, creating greater mismatching with time.

Therefore, it has been concluded that meaningful exchange of information based on grouping medical devices between different jurisdictions (e.g., for post-market surveillance, safety, effectiveness) is only possible with a single harmonized medical device nomenclature.

### **Article highlights**

- This work evaluates the feasibility of a direct term-to-term mapping of the GMDN to the EMDN used for naming and grouping medical devices.
- Our study involved, for each general medical device GMDN Term, a manual comparison to all EMDN terminal terms and selecting the closest corresponding EMDN term.
- The majority of the GMDN Terms corresponded to ‘other/various’ EMDN terminal terms.
- The ‘other/various’ EMDN terminal terms are not a useful tool to support cross-jurisdiction data analysis because they are non-homogenous concepts grouping devices with potentially different features.
- In our opinion, this is not an effective approach to the global harmonization of medical devices.

### **Declaration of interest**

The authors are employed by the GMDN Agency which publishes the GMDN. They have no affiliation or financial involvement with the European Commission which publishes the EMDN, or the WHO.

### **Funding details**

This work was funded by the GMDN Agency.

### **Data Availability Statement**

A sample of the mapping data is available upon [request](#). The full data set is work carried out and owned by the GMDN Agency and cannot be published.

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