



# GMDN issues

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# GMDN at MPA Sweden

Medicinteknik - Produkt

Arkiv Visa Arbetsyta

**Sökkriterier för produkt** Sök prod./prod. omr. Sökresultat [311] Sökresultat produktområden

Produkt	Artikelnr	PID	Prodklass	Riskklass	Tillverkare	Prod
Armory (tidigare Arenadigit)		114603	CE	MD, I	Rehabus AB	Reg
Armbike 12"	002	94026	CE	MD, I	ARMBIKE	Reg
Armbike 16"	006	94025	CE	MD, I	ARMBIKE	Reg
Armbike 20"	010	94024	CE	MD, I	ARMBIKE	Reg
Armbike 28"	011	94023	CE	MD, I	ARMBIKE	Reg
Armbike kit	061	94022	CE	MD, I	ARMBIKE	Reg
Armbörd	100 30	16754	CE	MD, I	Remeda AB	Reg
Armbordsklocka / Clock for ar	10018	65965	CE	MD, I	Reinert Medical AB	Reg

**Produktregister** Eudamedstatus: Created

Produktname: Armbike 20"  
 Artikelnummer: 010 PID: 94024 Reg: Swe Eng  
 Produktbeskrivning: Armdriven 3-hjulig cykel med 2hjul bak och ett hjul fram. framhjulet är drivhjulet vilket driver cykeln framåt med styret i en rotdrirelse.  
 Produktklass: CE-märkt  
 Riskklass: MD, Klass I  
 GMDN: 31141, Assistive foot-propelled bicycle  
 Kategori: 11 Hjälpmedel för funktionshindra Avreg. datum

**Sökning, GMDN**

Term: bicycle  
 Kod:  
 Definition:  
 Sök alla kategorier  
 Sök

Term	Kod	Definition	Kategori
Bicycle exerciser	10385	An exercise apparatus designed to provide the same physical acti...	04, 11
Assistive foot-propelled bicycle	31141	A vehicle with two wheels mounted on a slender frame on which t...	11
Assistive hand-propelled bicycle	38815	A vehicle with two wheels mounted on a slender frame on which t...	11
Wheelchair bicycle connector		A vehicle with two wheels mounted on a slender frame which the user with a disability sits astride and pedals with their legs to provide a means of transportation, typically without the attendance of another person. It is designed to be operated by the user. The vehicle will enhance the user's independence in short- to medium-range transportation.	

**Relaterade**

- 01 Aktiva implantat
- 02 Anestesi- och andningsstödande produkter
- 03 Dentalprodukter
- 04 Elektromekaniska medicintekniska produkter
- 05 Sjukhusutrustning
- 06 In vitro diagnostiska produkter
- 07 Implantat, ej aktiva
- 08 Ögon- och synhjälpmedel
- 09 Instrument, flegågs
- 10 Engångsartiklar
- 11 Hjälpmedel för funktionshindrade
- 12 Diagnostiska o behandlande strålningsprodukt
- 13 Produkter för alternativa behandlingsmetoder
- 14 Produkter av biologiskt ursprung
- 15 Fastighetsrelaterade produkter
- 16 Laboratorieutrustning, generell
- 17 Medicinsk programvara

Diarienummer: 451:2010/3, 452:2011/3, 452:2012/3

Visa bara preferred terms

OK Avbryt

# GMDN Agency web site

The screenshot shows a web browser window with the URL <http://www.gmdnagency.com/MyUpdates.aspx>. The navigation menu includes: [GMDN Home Page](#), [About GMDN](#), [Membership](#), [FAQ](#), [Contact Us](#), and [Logout](#). The main navigation bar contains: [My GMDN](#) (highlighted with a red box), [Terms](#), [Search](#), [Navigator](#), [Information](#), [Basket](#), and [Request a Code](#). Below this, there are buttons for [Settings](#), [Get Update Data](#) (highlighted), and [Download Old Update](#). The content area displays two sections: **Get GMDN data file** with the text "Last time you received GMDN data file on 2012/10/01 06:10" and "You have 23 day(s) till you will be able to get GMDN data file.", and **Get an updates.** with the text "Last time you received updates on 2012/10/31 15:00" and "Next time you can get updates in 23 day(s)".

# gmdnReport.xml

```
<?xml version="1.0"?>
<gmdn>
  <group>
    <GMDNCode value="56764"/>
    <termName value="Adrenocorticotrophic hormone (ACTH) IVD, antibody"/>
    <synonymCode value="0"/>
    <templateSpecifier value="0"/>
    <definition value="One or multiple immunoglobulins capable of binding to specific antigenic determinants and intended to be used for the qualita
  <categories>
    <category value="6"/>
  </categories>
  <status value="Active"/>
  <productSpecifier value="Product Identifier"/>
</group>
  <group>
    <GMDNCode value="41795"/>
    <termName value="Adrenocorticotrophic hormone (ACTH) IVD, calibrator"/>
    <synonymCode value="0"/>
    <templateSpecifier value="0"/>
    <definition value="A material which is used to establish known points of reference for an assay intended to be used for the qualitative and/or qu
  <categories>
    <category value="6"/>
  </categories>
  <status value="Active"/>
  <productSpecifier value="Product Identifier"/>
</group>
  <group>
    .
  </group>

```

# GMDN in EUDAMED

European Commission > Health and Consumers > Eudamed

Home Medical Device Management Advanced Search Download **Upload** Reports Help CA: S

Uploads

List of Uploads

No	Owner	Upload file name	CIE Type	Upload Date	Status	Results	View
1	SE-CA-001	SE-CA-001_20121106081400.2...	No	2012-11-06	Uploaded	Success.xml	Ref
2	SE-CA-001	SE-CA-001_20121106081136.2...	No	2012-11-06	Uploaded	Success.xml	Ref
3	SE-CA-001	SE-CA-001_20121106080939.2...	No	2012-11-06	Uploaded	Success.xml	Ref
4	SE-CA-001	SE-CA-001_20121106080636.2...	No	2012-11-06	Uploaded	Success.xml	Ref
5	SE-CA-001	SE-CA-001_20121029162352.2...	No	2012-10-29	Uploaded	Success.xml	Ref
6	SE-CA-001	SE-CA-001_20121029094535.2...	No	2012-10-29	Uploaded	Success.xml	Ref
7	SE-CA-001	SE-CA-001_20121029094331.2...	No	2012-10-29	Uploaded	Success.xml	Ref
8	SE-CA-001	SE-CA-001_20121029094110.2...	No	2012-10-29	Uploaded	Success.xml	Ref
9	SE-CA-001	SE-CA-001_20121029093921.2...	No	2012-10-29	Uploaded	Success.xml	Ref
10	SE-CA-001	SE-CA-001_20121023153759.2...	No	2012-10-23	Uploaded	Success.xml	Ref
11	SE-CA-001	SE-CA-001_20121016080918.2...	No	2012-10-16	Uploaded	Success.xml	Ref

Page 1 (Item 1 to 24)

Upload

New Upload

Clinical Investigation :

File:

Validate Upload Cancel

Reference List

- Eudamed-v6.xsd 2011-02-21
- Eudamed-CI.xsd 2011-02-21
- Competent Authorities code: 2012-10-23
- Message Description: 2010-09-01
- Country code: 2007-02-02
- GMDN code: 2012-10-31**
- GMDN Obsolete code: 2007-10-15**
- Notified bodies code: 2012-10-08

# GMDN in EUDAMED

Reference List		
<b>Eudamed-v6.xsd</b>		<b>2011-02-21</b>
<b>Eudamed-CI.xsd</b>		<b>2011-02-21</b>
<b>Competent Authorities code:</b>		<b>2012-10-23</b>
<b>Message Description:</b>		<b>2010-09-01</b>
<b>Country code:</b>		<b>2007-02-02</b>
<b>GMDN code:</b>		<b>2012-10-31</b>
<b>GMDN Obsolete code:</b>		<b>2007-10-15</b>
<b>Notified bodies code:</b>		<b>2012-10-08</b>

# GMDN in EUDAMED

- **GMDN Code: GMDN.xml**

Updated every two weeks.

We use this file for validation of our uploads.

Q: Possible to get notified when new file exists? Or even better, automatically e-mailed?

# GMDN in EUDAMED

- **GMDN Obsolete Code: GMDN\_OBS.xml**

Accepted for validation

Q: Purpose of this file? Why not included in GMDN.xml?



# GMDN in EUDAMED

- **“Brand new” GMDN codes**

**Q: How should we handle the case when we have GMDN codes that are so new that they haven't yet been included in Eudamed (GMDN-xml)?**

**Suggestion: Possible for EUDAMED to get daily updates from GMDN Agency?**

# Other questions/discussions

- **How is GMDN implemented in other CA systems?**
- **GMDN Policy Advisory Group: Progress?**
- **Invite GMDN Agency to our WG for a presentation?**

# Problems with updates from GMDN Agency

In the update file we have:

```
<group>
<GMDNCode value="45022"/>
<termName value="Bum dressings"/>
<synonymCode
value="34084,43186,58978,59234,47693,47763,47764,47
<templateSpecifier value="0"/>
<definition value=""/>
<categories>
</categories>
<status value="Active"/>
<productSpecifier value="Not for Product
Identification"/>
</group>
```





*Thank you*