



Digital assets

Medical device specifications and guidelines
– Healthcare sector

Version number 1.0, Final, February 2023



Summary

Document property	Value
Name	Digital assets
Date	February 2023
Version	1.0
Status	Final
Description	Medical device specifications and guidelines – healthcare sector

Version control

Version	Date	Modified by	Summary of revision
1.0	February 2023	Sarina Pielaat Melissa Veldman Jolyn van der Beek Sietse Houtman Kristel Schouwenburg Johanneke Wolters	Document created for digital assets for the medical device category within the healthcare sector.

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Introduction

In addition to reliable product information and product images, supply chain partners need more and more documents (digital assets): for internal processes and to make data exchange easier.

Digital assets – just like product information and product images – can also be shared via the Global Data Synchronization Network (GDSN). In the Netherlands, this is done via GS1 Data Source.

The guidelines for these product images can be found in the second chapter.

Digital assets

This document states which other types of digital assets (IFU, DoC, CE, cleaning, disinfection and sterilization instructions) suppliers can share and which attributes are used for this.

The list of digital assets with corresponding definitions that forms the basis for this document is based on the [GS1 Global Standard](#).

1 Digital assets

Specifications and ways to share a digital asset.

How can you share digital assets?

- Suppliers with their own public Digital Asset Management (DAM) system can share the assets with customers via a URL (link).
- Vendors using _ GS1 Data Source can also upload the digital asset file in GS1 Data Source. This is explained in Appendix 1.
- Suppliers with their own connection (M2M) with a GDSN certified data pool can also share the digital asset via the GDSN certified data pool. The fields for this are in the module 'referencedFileDetailInformationModule'. In the 'FieldDefinitions' tab of the ECHO data model, the details about these fields can be found using the BMS ID.

From section 1.2 on, for each type of asset that is relevant within the sector, information is given on how the type can be shared.

1.1 Attributes of digital assets

The attributes below are used for sharing digital assets. But sometimes it is necessary to also fill in attributes for the product itself, for example for a certificate. More details about these attributes can be found in the data model. The most recent version can be found on the website of GS1 Netherlands.

Points to consider

- We advise you to always share the URL (link) to the supplied document from suppliers, for example an IFU, unchanged via the GS1 data pool with customers. This will share the most recent version of the document.
- One digital asset is often valid for multiple items. In the data pool, you must link this digital asset to each individual item (GTIN). In GS1 Data Source it is not possible to link a digital asset to multiple articles at the same time.
- PDF files should always be shared without clipping paths and in a compressed (light) version.

BMS ID	Attribute	Example	Explanation
2999	Type external file (referencedFileTypeCode)	IFU	The type of file, for example, a manufacturer or brand logo of the product.
3000	Link to external file (uniformResourceIdentifier)	Example link	The URL that allows the digital asset to be viewed or stored.
2994	External file language code (fileLanguageCode)	NL	Language code for the digital assets (if applicable).
7206	File format name external source (fileFormatName)	PDF	The format of the external source, for example, TIFF, JPG, PDF, or GIF.
2995	Standard file name (fileName)	[fileName]_IFU_NL	To share digital assets, you do not need to include the GTIN (14 digits, e.g. 08712345678906) in the file name. One asset is often relevant for multiple products. For product images this is mandatory. Create the file name as follows: file name, followed by what type of digital asset it is and optionally the mention of the language code if you share the asset in multiple languages.
2989	File end date (fileEffectiveEndDateTime)	2025-02-25T00:00:00	Date until when the file is valid. This can be important for certificates, for example.
2990	Effective date of the file (fileEffectiveStartDateTime)	2021-02-25T00:00:00	Date from which the file is valid. This can be important, for example, for an EU declaration of conformity or manual.

1.2 Digital assets – Healthcare

Description of the digital assets that healthcare providers are asking to record in GDSN.

1.2.1 DoC – Declaration of Conformity

A DoC, or Declaration of Conformity, is a document with which the manufacturer declares that the product complies with European directives; also called the EU declaration of conformity. By signing the EU declaration of conformity, the manufacturer declares to be fully responsible for the fact that the product complies with the applicable EU legislation.

The DoC of the product can be shared via a URL (link) or a PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	DECLARATION_OF_CONFORMITY
3000	Link to external file (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_EU_Declaration_Of_Conformity_DigitalAssets_08022023.pdf

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	DECLARATION_OF_CONFORMITY
2995	Standard company name (fileName)	[fileName]_DECLARATION_OF_CONFORMITY_EN

1.2.2 CE – certificate

A CE (*Conformité Européene*), or a certificate, is a document issued by a notified body, in which the Notified Body declares that the device is safe and recognized according to the European Directive or Regulation (MDD, IVDD, AIMDD, MDR or IVDR).

The certificate of the product can be shared via a URL (link) or a PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	CERTIFICATION
3000	Link to external file (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_EU_Certificate_DigitalAssets_06022023.pdf

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	CERTIFICATION
2995	Standard company name (fileName)	[fileName]_Certification_EN

1.2.3 IFU – instructions for use

An IFU, or Instructions For Use, is an instruction manual. The instructions for use is the information provided by the manufacturer to inform the user of the intended purpose and proper use of a device and the precautions to be taken.¹

The IFU of the product can be shared via a URL (link) or a PDF.

If the IFU does not contain cleaning, disinfection and sterilization instructions, you will also share the asset cleaning, disinfection and sterilization instructions in addition to the IFU.

The user manual of the product can be shared via a URL (link) or a PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	IFU
3000	Link to external file (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_IFU_DigitalAssets_08022023.pdf

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Type extern bestand (referencedFileTypeCode)	IFU
2995	Standard company name (fileName)	[fileName]_IFU_EN

1.2.4 Including cleaning, disinfection and sterilization instructions

An IFU including cleaning, disinfection and sterilization instructions, or an Instructions For Use including cleaning, disinfection and sterilization instructions, is a document issued by the manufacturer to inform the user about the intended purpose and proper use of a device and the precautions to be taken.

The IFU including cleaning, disinfection and sterilization instructions of the product can be shared via a URL (link) or a PDF. The IFU including cleaning, disinfection and sterilization instructions of the product can be shared via a URL (link) or a PDF.

If the IFU and cleaning, disinfection and sterilization instructions concern two separate documents. Then you share two separate assets: the IFU (see 1.2.3) and the cleaning, disinfection and sterilization instructions (1.2.5).

This instruction can be shared via a URL (link) or PDF.

¹ REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 5 April 2017 - on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC (europa.eu)

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	IFU_INCLUDING_CLEANING_DISINFECTION_STERILIZATION_INSTRUCTIONS
3000	Link to external file (uniformResourceIdentifier)	No example available

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	IFU_INCLUDING_CLEANING_DISINFECTION_STERILIZATION_INSTRUCTIONS
2995	Standard file name (fileName)	[file Name]_IFU_INCLUDING_CLEANING_DISINFECTION_STERILIZATION_INSTRUCTIONS_EN

1.2.5 Cleaning, disinfection and sterilization instructions

The cleaning, disinfection and sterilization instructions applicable to the product. These may be in accordance with EN-ISO 17664.

The cleaning, disinfection and sterilization instructions of the product can be shared via a URL (link) or a PDF.

If the cleaning, disinfection and sterilization instructions are not included in the Instructions For Use, also share the IFU itself (see 1.2.3)

This instruction can be shared via a URL (link) or PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Type external file	CLEANING_DISINFECTION_STERILIZATION_INSTRUCTIONS
3000	Link to external file	No example available

Veldnamen bij het uploaden van een PDF

BMS ID	Attribute	Example
2999	Type external file (referencedFileTypeCode)	CLEANING_DISINFECTION_STERILIZATION_INSTRUCTIONS
2995	Standard company name (fileName)	[Naam_Bestand]_CLEANING_DISINFECTION_STERELISATION_INSTRUCTIONS_EN

2 Product Images

To capture product images according to the right standards and guidelines, you can use the standard 'GS1 Product Image Specification Standard'.

Apart from the introduction and the technical specifications (first and second chapters from the standard), the following sections, among others, are important:

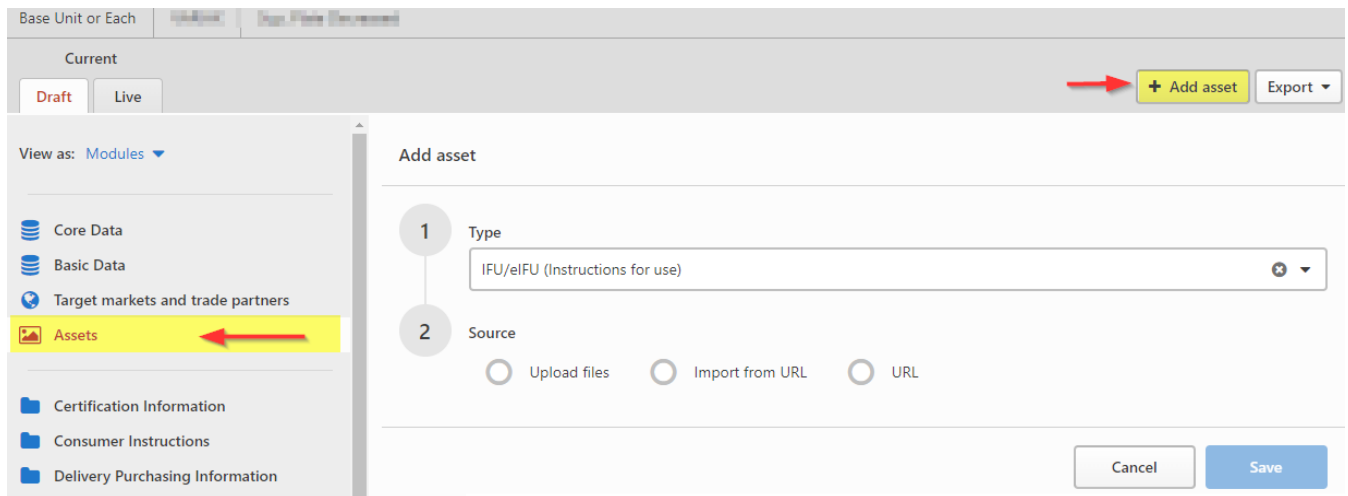
- Chapter 3 - Primary image
- Chapter 6.5 - Pharmaceutical Drugs/Medical Devices

3 Appendices

Appendix 1: Deliver digital assets via GS1 Data Source

Below is a brief explanation of how digital assets can be added in GS1 Data Source.

- Go to module 'Media', in the draft version of the item
- Click + Add Media
- Select the type of digital asset
- Select the source 'Upload files' or 'Import from URL'
- Upload files or import a URL
- Save and publish the digital assets to customers



The screenshot shows the GS1 Data Source interface. At the top, there are tabs for 'Base Unit or Each' and 'Sign. File Document'. Below that, there are 'Draft' and 'Live' buttons. A red arrow points to a '+ Add asset' button. On the left, a sidebar shows a list of modules: 'Core Data', 'Basic Data', 'Target markets and trade partners', 'Assets' (highlighted with a red arrow), 'Certification Information', 'Consumer Instructions', and 'Delivery Purchasing Information'. The main area is titled 'Add asset' and contains two numbered steps: 1. Type, with a dropdown menu showing 'IFU/eIFU (Instructions for use)'; and 2. Source, with three radio button options: 'Upload files', 'Import from URL', and 'URL'. At the bottom right, there are 'Cancel' and 'Save' buttons.

Via Excel

For the delivery of digital assets/media documents via Excel, see 'Manual: uploading URL via Excel'.

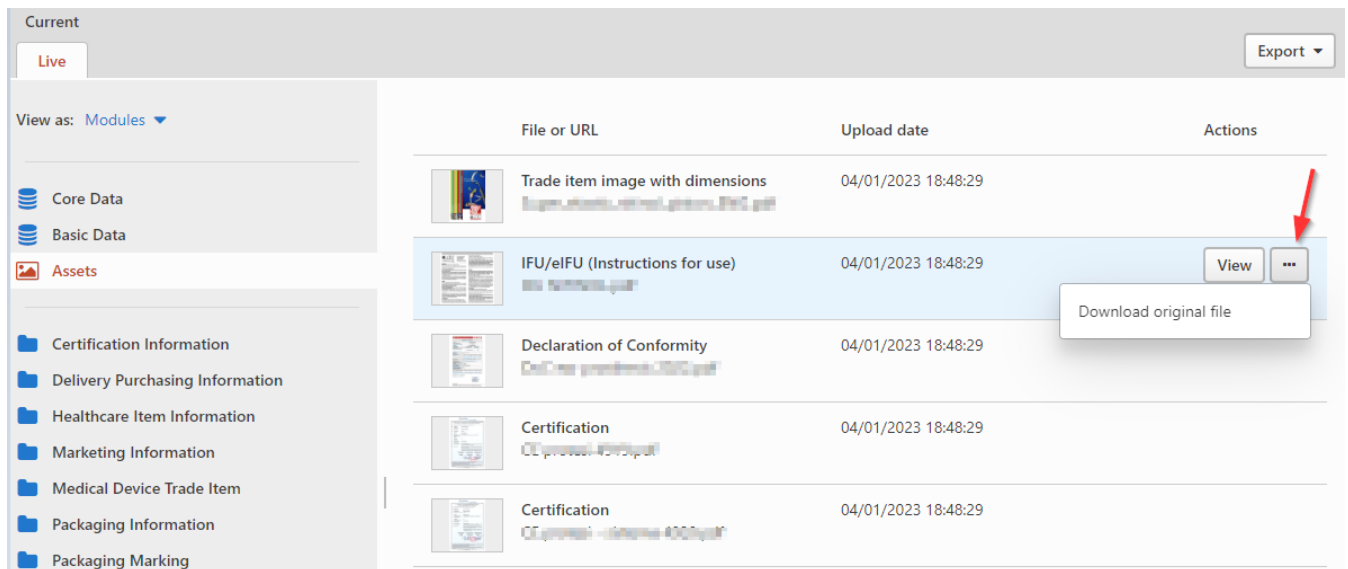
Appendix 2: Retrieve digital asset

The URL of digital assets/media documents is provided by default in the XML message via the FTPs or AS2 connection. When you retrieve all data from articles via the API, the URL via JSON is included by default.

Via GS1 Data Source

Below is a brief explanation of how to retrieve digital assets from GS1 Data Source:

- Go to module 'Media' in the item.
- Select the digital asset you want to download.
- Detail and three dots will appear on the right side of the screen.
- Click on the three dots and select Download original file.
- At the top right, there is also the button to export the article to Excel. The URL of each of the shared assets can be found in the tab 'ReferencedFileDetailInformation'.

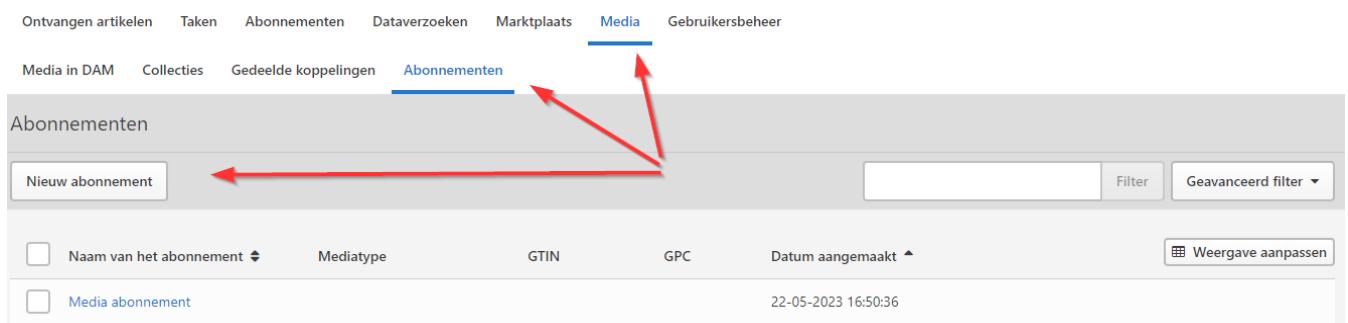


The screenshot shows the 'Current' view of a digital asset in the GS1 Data Source. The interface includes a 'Live' status indicator and an 'Export' button. A sidebar on the left lists various data modules, with 'Assets' selected. The main area displays a table of digital assets with columns for 'File or URL', 'Upload date', and 'Actions'. The 'IFU/eIFU (Instructions for use)' asset is highlighted, and a dropdown menu is open under its 'Actions' column, showing the option 'Download original file'. A red arrow points to this option.

File or URL	Upload date	Actions
Trade item image with dimensions Image: trade item image with dimensions 2023.pdf	04/01/2023 18:48:29	
IFU/eIFU (Instructions for use) IFU: IFU_eIFU.pdf	04/01/2023 18:48:29	View ... Download original file
Declaration of Conformity DoC: Declaration of Conformity 2023.pdf	04/01/2023 18:48:29	
Certification CE: CE mark 2023.pdf	04/01/2023 18:48:29	
Certification CE: CE mark 2023.pdf	04/01/2023 18:48:29	

It is also possible to download digital assets in bulk:

- Go to the Media tab in GS1 Data Source.
- Under the Subscriptions tab, create a subscription to the Data supplier from whom you want to download digital assets.
- Within a few hours, the digital assets are visible and can be retrieved under the Media tab in DAM or under Shared Links.



The screenshot shows the 'Media' tab in the GS1 Data Source interface. The 'Abonnementen' (Subscriptions) sub-tab is active. A red arrow points to the 'Nieuw abonnement' (New subscription) button. The interface includes a search bar, a 'Filter' button, and a 'Geavanceerd filter' (Advanced filter) dropdown. Below the search bar, there is a table with columns for 'Naam van het abonnement' (Subscription name), 'Mediatype' (Media type), 'GTIN', 'GPC', and 'Datum aangemaakt' (Created date). A 'Weergave aanpassen' (Adjust display) button is also visible.

Naam van het abonnement	Mediatype	GTIN	GPC	Datum aangemaakt
<input type="checkbox"/> Media abonnement				22-05-2023 16:50:36