Digital Files and Product Images

Specifications and guidelines for Medical Devices - sector Healthcare

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Introduction

Next to reliable product information and product images, Supply chain partners need more and more documents (digital files): for internal processes and to make data exchange easier.

Digital files - like product information and product images - can also be shared via the Global Data Synchronisation Network (GDSN). In the Netherlands, this is done via GS1 Data Source.

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

Digital files

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

The list of digital files with associated definitions that forms the basis for this document is based on the *GS1 Global standaard*.

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1 Digital files

Specifications and means to share a digital file.

How can you share digital files?

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

From section 1.2 onwards, details on how to share each asset type relevant within the sector are given.

1.1 Attributes digital files

The attributes below are used for sharing digital files. Sometimes it is also necessary to fill in attributes for the product itself, e.g. for a certificate. More details on these attributes can be found in the data model. The most recent version can be found on the GS1 Netherlands website.

Points of attention

- We recommend always sharing the URL (link) to the supplied document from suppliers, e.g. an IFU, as is via the GS1 data pool with customers. This way, the most recent version of the document is shared.
- One digital file is often valid for multiple items. In the data pool, however, you need to link these digital files to each individual article (GTIN). It is not possible in GS1 Data Source to link a digital file to multiple articles at the same time.
- Pdf files must always be shared without clipping paths and in a compressed (light) version.

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BMS ID	Attribute	Example	Remarks
2999	Referenced File Type Code referencedFileTypeCode)	IFU	The type of file, e.g. a manufacturer or brand logo of the product.
3000	Uniform Resource Identifier (uniformResourceIdentifier)	Example link	The URL through which the digital file can be viewed or saved.
2994	File Language Code (fileLanguageCode)	NL	Language code for the digital files (if applicable).
7206	File Format Name (fileFormatName)	PDF	The format of the external source, e.g. TIFF, JPG, PDF or GIF.
2995	File Name (fileName)	[File Name]_IFU_NL	For digital file sharing, you do not need to include the GTIN (14 digits, e.g. 08712345678906) in the file name. This is because one asset is often relevant for several products. For product images, however, this is mandatory. Build the file name as follows: file name, followed by what type of digital file it is and possibly the language code if you share the asset in several languages.
2989	File Effective End Date Time (fileEffectiveEndDateTime)	2025-02-25T00:00:00	Date until which the file is valid. This may be important for certificates, for example.
2990	File Effective Start Date Time (fileEffectiveStartDateTime)	2021-02-25T00:00:00	Date from when the file is valid. This can be important, for example, for an EU declaration of conformity or manual.

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1.2 Digital files – Healthcare

Description of the digital files requested by healthcare organisations to be captured in GDSN.

1.2.1 DoC – Declaration of Conformity

A DoC, or Declaration of Conformity, is a document by 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 product's compliance to 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	Referenced File Type Code (referencedFileTypeCode)	DECLARATION_OF_CONFORMITY
3000	Uniform Resource Identifier (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_EU_Declaration_Of_Conformity_DigitalAssets_08022023.pdf

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	DECLARATION_OF_CONFORMITY
2995	File Name (fileName)	[File name]_DECLARATION_OF_CONFORMITY_EN

1.2.2 CE – certificate

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

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

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	CERTIFICATION
3000	Uniform Resource Identifier (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_EU_Certificate_DigitalAssets_06022023.pdf

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Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	DECLARATION_OF_CONFORMITY
2995	File Name (fileName)	[Naam bestand]_Certification_EN

1.2.3 Document

A document is a file (without specific conditions) that can be attached to a GTIN.
Because of the transition from directives (MDD/IVDD/AIMDD) to legislation (MDR/IVDR), CE certificates will change. In the transition period, products can still be sold under the old directives despite the fact that the CE certificate has expired. The 'self-declaration' document can be shared via a URL (link) or a PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	Document
3000	Uniform Resource Identifier (uniformResourceIdentifier)	*230609-final_mdr_manufacturer-declaration.docx*

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	Document
2995	File Name (fileName)	[File name]_DOCUMENT_EN

1.2.4 IFU – instructions for use

An IFU, are the instructions for use. The instructions for use is the information provided by the manufacturer to inform the user about 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 sterilisation instructions, share the asset Cleaning, disinfection and sterilisation instructions in addition to the IFU.

The product's instructions for use can be shared via a URL (link) or a PDF.

[1] REGULATION (EU) 2017/ 745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 5 April 2017 - concerning 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)

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Field names when uploading a URL

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	IFU
3000	Uniform Resource Identifier (uniformResourceIdentifier)	http://images.gs1.nl/Voorbeeld_IFU_DigitalAssets_08022023.pdf

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	IFU
2995	File Name (fileName)	[Naam bestand]_IFU_EN

1.2.5 IFU including cleaning disinfection sterilisation instructions

An IFU including cleaning, disinfection and sterilisation instructions, or Instructions For Use including cleaning, disinfection and sterilisation instructions, is a manufacturer's document 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 sterilisation instructions of the product can be shared via a URL (link) or a PDF.

Share 2 separate assets: the IFU (see 1.2.3) and the Cleaning, disinfection and sterilization instructions (1.2.5). If the IFU and cleaning, disinfection and sterilization instructions are 2 separate documents.

These instructions can be shared via a URL (link) or PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	IFU_INCLUDING_CLEANING_DISINFECTION_STERILISATION_INSTRUCTIONS
3000	Uniform Resource Identifier (uniformResourceIdentifier)	Geen voorbeeld beschikbaar

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	IFU_INCLUDING_CLEANING_DISINFECTION_STERILISATION_INSTRUCTIONS
2995	File Name (fileName)	[Naam bestand]_IFU_INCLUDING_CLEANING_DISINFECTION_STERILISATION_INSTRUCTIONS_EN

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1.2.6 Cleaning, disinfection and Sterilization instructions

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

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

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

These instructions can be shared via a URL (link) or PDF.

Field names when uploading a URL

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	CLEANING_DISINFECTION_STERILISATION_INSTRUCTIONS
3000	Uniform Resource Identifier (uniformResourceIdentifier)	No example available

Field names when uploading a PDF

BMS ID	Attribute	Example
2999	Referenced File Type Code (referencedFileTypeCode)	CLEANING_DISINFECTION_STERILISATION_INSTRUCTIONS
2995	File Name (fileName)	[File_Name]_CLEANING_DISINFECTION_STERELISATION_INSTRUCTIONS_EN

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2 Productimages

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

The parts that are important here and are further explained in the following sections are:
- Chapter 1, an introduction regarding product images
- Chapter 2, the technical specifications regarding product images
- Chapter 3, the primary image
- Chapter 6.5, information on pharmaceutical drugs/medical devices

2.1 Introduction productimages

The Default Front
The Default Front of a product is determined by the GS1 Package and Product Measurement Standard. All other sides in relation to the front of the product can be identified with a numerical extension. Other sides are captured automatically as the numeric extension allows multiple images (and sides) for the same GTIN.

Clipping path
A clipping path is used to cut out a subject or element of a 2D image in image editing software. Everything within the clipping path can be kept and the elements outside the clipping path can be removed if desired. This means that the original background of the product image can be removed and the object can then be placed in front of any desired background.

With Computer Generated Imagery programmes (CGI programmes), files can be rendered/saved with transparent backgrounds, making the application of a clipping path unnecessary.

TIFF files can be saved with a transparent background. To avoid creating the clipping path in an image editing programme, you can remove the background with the opened layer on the subject. However, it is strongly recommended to add the clipping path and flatten images with a white background to manage image size for storage and delivery.

2.2 Technical specifications

Professional equipment optimises the results of product images. The 'GS1 Product Image Specification Standard (Chapter 2 Technical recommendations)' goes into the technical details for creating and editing product images.

For products to be photographed, they should be photographed in packaging, out of packaging or both. If there is any doubt about which state is most appropriate to best represent the product, both should be taken and properly identified. This decision should be made together with the data provider.

2.3 Primary image

Primary images are images that, by themselves, can represent the product. These include Product Image (web & high resolution) with or without supporting elements.

- File format TIFF, JPEG, PNG or Thumbnail
- File size 900 x 900 pixels - 2400 x 2400 pixels
- White background RGB 255/255/255

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The base name of the file is required to consist of at least 19 characters with an optional addition.
The structure is as follows:

Mandatory

Positie	1-14	15	16	17	18	19
Data	**GTIN**	**Underscore**	**Image type**	**Facing**	**Orientation**	**State**
Value	(n14)	_	A – Primaire Image web	0 – Not Applicable	C – Centre	(1) In packaging
				1 – Front	L – Left	(2) Out of packaging
				2 – Left	R – Right	(A) Case
				3 - Top	N – No plunge Angle	(B) Innerpack
				7 - Back		(M) Open Case
				8 - Right		(P) Pallet/Display
				9 - Bottom		

GS1 recommends using TIFF for storing product images. These files can be easily converted to other file formats.

2.4 Information pharmaceutical drugs /medical devices

Pharmaceutical drugs/medical devices product images refer to products used in the diagnosis, treatment or prevention of disease that achieve their primary purpose by pharmacological, immunological or metabolic means in or on the body. Includes medical equipment and supplies, any drug, biological product or therapeutic food for human application.

- File format JPG
- File size 1500 x 1500 pixels
- White background RGB 255/255/255

The base name of the file must consist of at least 21 characters with an optional addition of the language code. The structure is as follows:

Position	1-14	15	16	17	18	19	20	21	22	23
Data	GTIN	Under score	Componen t level	Sequence component level	Component type	Under score	Image type	Facing	Under score	Language
Value	(n14)	-	(n)	(n)	0 – product 1 – Peel 2 - accessories 3 – Unit of use 4 – Orid Solid Dosage	-	G - Pharmaceutical Drugs/Medical Devices	0 - Not applicable 1 – Front 2 - Left 3 – Top 7 – Back 8 – Right 9 - Bottom	-	EN FR

Explain example:

- Level 1: box with barcode
- Level 2: Inhaler + attachment

For the naming of items, the following applies.

- **Outer packaging**. The box with barcode is the first component and gets on character 16 and 17 a '1'. Since it is a product, it gets code '110' on characters 16, 17 and 18.
- **Unit of use and Accessory**. The box contains an inhaler and an attachment. The inhaler gets a 2 as component level, and the inhaler a 1 as component order level, the attachment (like the inhaler) gets a 2 as component level. The component level here also gets a 2, because it is a second item, in addition to the inhaler.

Example file name:

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Outer Packaging

00000000000000_110_G1

00000000000000_110_G2

00000000000000_110_G7

00000000000000_110_G3

00000000000000_110_G8

00000000000000_110_G9

Unit of use

00000000000000_213_G1

00000000000000_213_G2

00000000000000_213_G7

00000000000000_213_G8

Accessory

00000000000000_222_G1

00000000000000_222_G2

00000000000000_222_G3

00000000000000_222_G7

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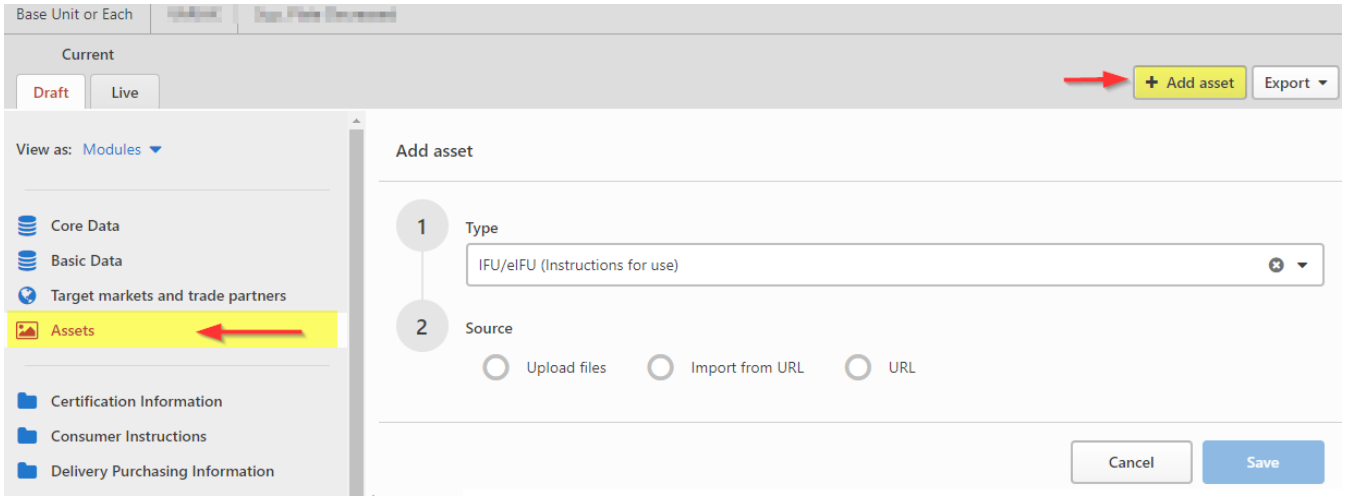
3 Appendices

Appendix 1: Digital files delivery via GS1 Data Source

Below is a brief explanation of how to add digital files in GS1 Data Source.

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



To submit digital files/media documents via Excel, please refer to 'Manual: uploading url via Excel'.

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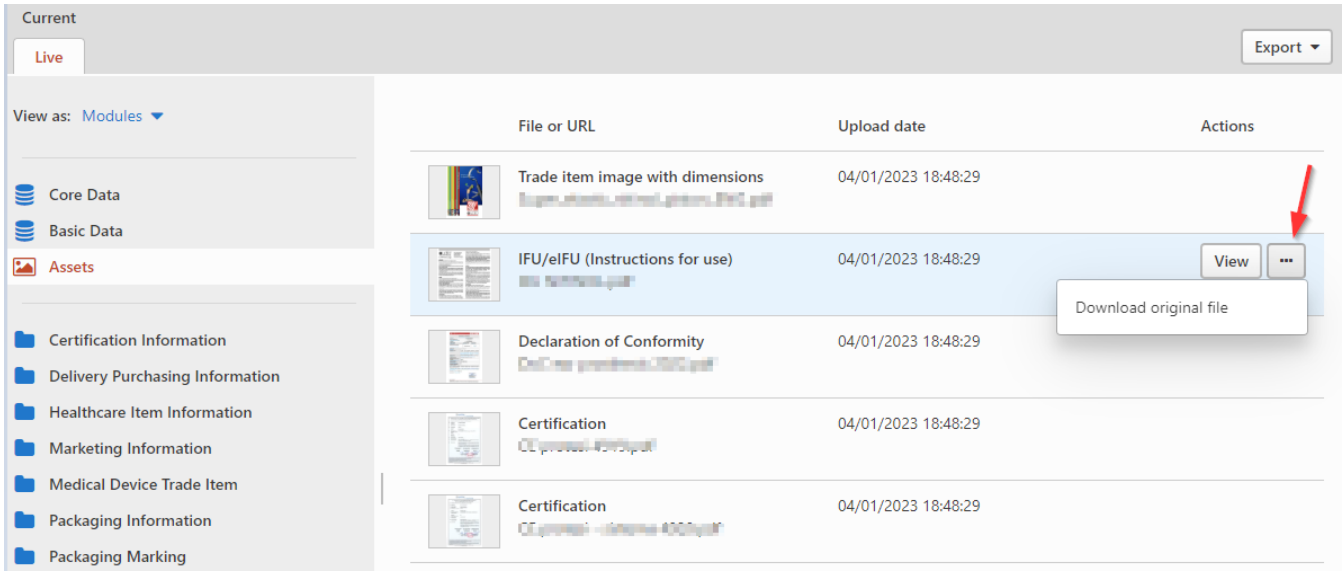
Appendix 2: Digital file retrieval

The URL of digital files/media documents is included by default in the XML message via the FTPs or AS2 connection. When bringing in all article data via the API, the URL via JSON is supplied by default

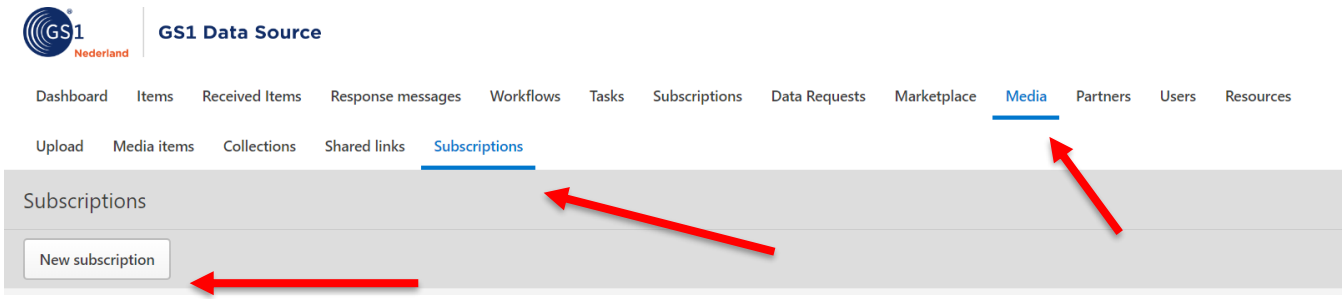
Via GS1 Data Source
Below is a brief explanation of how digital files can be retrieved from GS1 Data Source:

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



It is also possible to download digital files 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 the digital files.
- Within a few hours, the digital files will be visible and can be retrieved under the Media tab in DAM or under Shared Links.



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