



Implant Register Germany (IRD) - Handbook for manufacturers on how to create a CSV file for first-time entry of data into the product database for breast implants (PDB_BI) -	Date: 05 December 2023
	Annexes: --

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Purpose of the handbook

The aim of this handbook is to provide you as a manufacturer with a comprehensible overview of the product data needed for the IRD and help you create the CSV file for first-time entry of the data. All previous versions of this handbook are thus no longer applicable.

We recommend that the CSV file be sent via encrypted email to protect your product data. This requires a "key exchange" with us in advance. You will need a certificate from a recognised certification authority. Please contact your IT department for this. If you do not have a certificate, you can alternatively send your product data in a password protected zip file via unencrypted e-mail. Please contact our helpdesk (support-implantaregister@d-trust.net) or our telephone service hotline (+49 (0)30 2598-4316) before sending your product data to obtain further information on shipping.

To ensure that your data are uploaded to the product database quickly, please closely follow the completion instructions below. Any discrepancies in the details provided (e.g. with units, from/to details) mean that we will need to rework your data. This is a manual process and, as such, is prone to error.

Notes

- The attributes below must be entered line by line in a CSV file. An example can be found in this document.
- You must use a semicolon ; to separate the individual data attributes.
- The CSV file must be encoded using UTF-8 format.
- The product data are ultimately attributed to a manufacturer by logging into the product database. This process is secured using a foreign key relationship.
- Details that will be published in accordance with [Section 14 \(2\) IRegBV \(Implant Register Operating Ordinance\)](#) in conjunction with [Annex 1 No. I](#) are highlighted. These include:
 - Company name (of the manufacturer) and contact details of the product owner
 - Product or trading name
 - Identifying characteristics of the product
 - European Medical Device Nomenclature
 - The product identifier unique to the manufacturer and the product based on the UDI system (UDI Device Identifier – UDI-DI) including Basic UDI-DI
 - Catalogue or article number, product code or similar manufacturer-specific characteristics
- An example of the public list can be found later in this document.
- You can find an up-to-date list of the products already recorded in the product database as a PDF and CSV file under [Downloads](#) on this website with information for healthcare facilities. As we are still receiving data on an ongoing basis, we will update this list at according intervals.
- Although this document has been checked carefully, it is possible that it may contain errors. We would be happy to receive your feedback should you notice any errors.

List of the data fields

Field name	Data entry instructions
ArticleName	Name of the article as stated on the label; maximum length: 400 characters. Special characters such as ©, ™ and ® are not permissible and can be substituted with C, TM or R.
ArticleType	Breast implant or Breast expander
CatalogKeyArticleType	0190001 (for ArticleType=Breast implant) or 0190003 (for ArticleType=Breast expander)
CatalogKeyEmdn	P0601010101 or P0601010102 or P0601010199 or P0601010201 or P0601010202 or P0601010299 or P0601020101 or P0601020102 or P0601020199 or P0601020201 or P0601020202 or P0601020299 or P060199 or P060201 or P060299 (see https://webgate.ec.europa.eu/dyna2/emdn/# , the value for the lowest level in each case)
IsClinicalInvestigation	Yes or No
ClinicalInvestigationIdentifier	If IsClinicalInvestigation = Yes, then state the SIN . This will be possible once the CIPS module is released in EUDAMED. Until then, please leave this field empty.
Status	2 (for bulk upload, please always enter 2 = released)
IdentificationType	UDI¹ , Reference (REF) , Catalogue number or Other
CatalogueKeyIdentificationType	0068001 (for IdentificationType = UDI), 0068002 (for IdentificationType = Reference (REF)), 0068003 (for IdentificationType = Catalogue number) or 0068042 (for IdentificationType = Other)
IdentificationValue	State the GTIN, the REF, the Catalogue number or the Other value for unambiguous identification of the article

¹ There can only be one UDI per article! There can be several catalogue numbers alongside this one UDI, however, if the product is listed in several catalogues, for example.

IsPermanentExpander	If ArticleType = Breast expander, please state Yes or No , depending on whether the implant can remain in the body permanently. If ArticleType = Breast implant, please leave this field empty.
Cover	Silicone
CatalogueKeyCover	9992001
Surface	Smooth , Coated or Textured
CatalogueKeySurface	0128001 (for Smooth), 0128002 (for Coated) or 0128003 (for Textured)
TextureSurface	If Surface = Textured, please state Macro or Micro ; otherwise please leave this field empty.
CatalogueKeyTextureSurface	9993001 (for Micro) 9993002 (for Macro); otherwise please leave this field empty.
CoatingSurface	Polyurethane foam or Other material
CatalogueKeyCoatingSurface	9994001 (for Polyurethane foam) or 9994042 (for Other material)
CoatingSurfaceDescription	If CoatingSurface = Other material, the coating must be described in more detail here. Maximum length: 4,000 characters. Special characters such as ©, ™ and ® are not permissible and can be substituted with C, TM or R.
Filling	Saline solution , Silicone gel , Combination of silicone gel and saline solution or Other
CatalogueKeyFilling	0124001 (for Saline solution), 0124002 (for Silicone gel), 0124003 (for Combination of silicone gel and saline solution) or 0124042 (for Other)
FillingSiliconeGel	If Filling = Silicone gel, please select Different silicone gels ,

	<p>Silicone gel with additional materials (e.g. to reduce weight) or Silicone; otherwise please leave this field empty.</p>
CatalogueKeyFillingSiliconGel	<p>9995001 (for Different silicone gels), 9995002 (for Silicone gel with additional materials (e.g. to reduce weight)) or 9995003 (for Silicone)</p>
FillingDescription	<p>If Filling = Other, the filling must be described in more detail here. Maximum length: 4,000 characters. Special characters such as ©, ™ and ® are not permissible and can be substituted with C, TM or R.</p>
Shape	<p>Anatomical (teardrop-shaped), Round (point symmetrical) or Other</p>
CatalogueKeyShape	<p>0126001 (for Anatomical (teardrop-shaped)), 0126002 (for Round (point symmetrical)) or 0126042 (for Other); otherwise please leave this field empty.</p>
ShapeDescription	<p>If Shape = Other, the shape must be described in more detail here. Maximum length: 4,000 characters. Special characters such as ©, ™ and ® are not permissible and can be substituted with C, TM or R.</p>
Width	<p>State the width of the implant in [cm], format $^{[0-9]\{1.2\}}\{[0-9]\{0.1\}}$ (max. 2 digits before the comma, max. 1 decimal place). It is not necessary and not permissible to also state the unit.</p>
Height	<p>State the height of the implant in [cm], format $^{[0-9]\{1.2\}}\{[0-9]\{0.1\}}$ (max. 2 digits before the comma, max. 1 decimal place). It is not necessary and not permissible to also state the unit.</p>
Projection	<p>State the projection of the implant in [cm], format $^{[0-9]\{1.2\}}\{[0-9]\{0.1\}}$ (max. 2 digits before the comma, max. 1 decimal place). It is not necessary and not permissible to also state the unit.</p>
Volume	<p>State in [ccm, cm³, ml], format $^{[0-9]\{1.5\}}$ (max. 5 digits). For expanders, please state the maximum volume, not a range from ... to ...! It is not necessary and not permissible to also state the unit.</p>
Weight	<p>State in [g], format $^{[0-9]\{1.4\}}\{[0-9]\{0.2\}}$ (max. 4 digits before the comma, max. 2 decimal places). For expanders, please state the maximum weight, not a range from ... to ...! It is not necessary and not permissible to also state the unit.</p>

IsChip	Does the article have a chip? Yes or No
IsInjectionSystemPort	If ArticleType = Breast expander, please answer the question about the injection system with Yes or No ; otherwise please leave this field empty.
ValveType	If ArticleType = Breast expander, please select Integrated (magnetic valve) or Remote (with tube and port system) ; otherwise please leave this field empty.
CatalogueKeyValveType	9996001 (for Integrated (magnetic valve)) or 9996002 (for Remote (with tube and port system)); otherwise please leave this field empty.
IsSutureTabs	Does the implant have suture tabs? Yes or No
Mode	NEW (the MODIFIED mode is being considered, but first it needs to be determined which details in the product database can be changed without qualifying the product as a new product!)

Example of a CSV file

ArticleName;ArticleType;CatalogKeyArticleType;CatalogKeyEmdn;IsClinicalInvestigation;ClinicalInvestigationIdentifier;Status;IdentificationType;CatalogueKeyIdentificationType;IdentificationValue;IsPermanentExpander;Cover;CatalogueKeyCover;Surface;CatalogueKeySurface;TextureSurface;CatalogueKeyTextureSurface;CoatingSurface;CatalogueKeyCoatingSurface;CoatingSurfaceDescription;Filling;CatalogueKeyFilling;FillingSiliconGel;CatalogueKeyFillingSiliconGel;FillingDescription;Shape;CatalogueKeyShape;ShapeDescription;Width;Height;Projection;Volume;Weight;IsChip;IsInjectionSystemPort;ValveType;CatalogueKeyValveType;IsSutureTabs;Mode

IMRO Round Implant Low Profile;Breast implant;0190001;P0601010101;No;;2;UDI;0068001;00123456789012;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicone gel with additional materials (e.g. to reduce weight);9995002;;Round (point symmetrical);0126042;;8.0;8.0;2.4;100;125;No;;;;;NEW

Expand Round Implant Medium Profile;Breast expander;0190003;P060201;No;;2;UDI;0068001;00123456789015;No;Silicone;9992001;Textured;0128003;Micro;9993001;;;;;Saline solution;0124001;;;;;Anatomical (teardrop-shaped);0126042;;9.0;9.5;3.3;150;200;No;Yes;Integrated (magnetic valve);9996001;Yes;NEW

Bean T M Professional;Breast implant;0190001;P0601010102;Yes;SIN=123456;2;Other;0068042;BP-3274;;Silicone;9992001;Coated;0128002;;Other material;9994042;SuperCoating®;Combination of silicone gel and saline solution;0124003;;;;;Other;0126042;Pharaoh's delight;12.0;12.0;7.0;336;400;Yes;;;;;NEW

Smooth SpecialGel, Size A;Breast implant;0190001;P0601010101;No;;2;UDI;0068001;00123456789010;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicon;9995003;;Anatomical (teardrop-shaped);0126042;;8.0;8.5;2.5;100;150;No;;;;;NEW

Smooth SpecialGel, Size A;Breast implant;0190001;P0601010101;No;;2;Reference (REF);0068002;FGP0089019;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicone;9995003;;Anatomical (teardrop-shaped);0126042;;8.0;8.5;2.8;100;150;No;;;;;NEW

Smooth SpecialGel, Size B;Breast implant;0190001;P0601010101;No;;2;UDI;0068001;00123456789018;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicone;9995003;;Anatomical (teardrop-shaped);0126042;;9.0;9.5;3.1;125;175;No;;;;;NEW

Smooth SpecialGel, Size C;Breast implant;0190001;P0601010101;No;;2;UDI;0068001;00123456789017;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicone;9995003;;Anatomical (teardrop-shaped);0126042;;9.5;10.0;3.2;150;200;No;;;;;NEW

Smooth SpecialGel, Size D;Breast implant;0190001;P0601010101;No;;2;UDI;0068001;00123456789016;;Silicone;9992001;Smooth;0128001;;;;;Silicone gel;0124002;Silicone;9995003;;Anatomical (teardrop-shaped);0126042;;10.0;11.0;3.5;175;240;No;;;;;NEW

Example of the public list pursuant to Section 14 (2) IRegBV

Medical Implants and Devices International GmbH (M.I.D.I GmbH) Musterallee 45, 12040 Berlin, Germany			
Product or trading name	European no- menclature	Identifying characteristic	Value
IMRO Round Implant Low Profile	P0601010101	UDI	00123456789012
Expand Round Implant Medium Profile	P060201	UDI	00123456789015
Bean TM Professional	P0601010102	Other	BP-3274
Smooth SpecialGel, Size A	P0601010101	UDI	00123456789010
	P0601010101	Reference (REF)	FGP0089019
Smooth SpecialGel, Size B	P0601010101	UDI	00123456789018
Smooth SpecialGel, Size C	P0601010101	UDI	00123456789017
Smooth SpecialGel, Size D	P0601010101	UDI	00123456789016

Dropdown lists/Catalogue values

CatalogueKey	CatalogueName	Term_ENG
0190001	Kat_BI_ArtikelTyp	Breast implant
0190003	Kat_BI_ArtikelTyp	Breast expander
0080002	Kat_Implantattyp	Breast implant
9992001	Kat_BI_Huelle	Silicone
0128001	Kat_BI_Oberflaeche	Smooth
0128003	Kat_BI_Oberflaeche	Textured
0128002	Kat_BI_Oberflaeche	Coated
9993001	Kat_BI_Oberflaeche_Textur	Micro
9993002	Kat_BI_Oberflaeche_Textur	Macro
9994001	Kat_BI_Oberflaeche_Beschichtung	Polyurethane foam
9994042	Kat_BI_Oberflaeche_Beschichtung	Other material
0124002	Kat_BI_Fuellung	Silicone gel
0124001	Kat_BI_Fuellung	Saline solution
0124003	Kat_BI_Fuellung	Combination of silicone gel and saline solution
0124042	Kat_BI_Fuellung	Other
9995001	Kat_BI_Fuellung_Silikon	Different silicone gels
9995002	Kat_BI_Fuellung_Silikon	Silicone gel with additional materials (e.g. to reduce weight)
9995003	Kat_BI_Fuellung_Silikon	Silicone
0126002	Kat_BI_Form	Round (point symmetrical)
0126001	Kat_BI_Form	Anatomical (teardrop-shaped)
0126042	Kat_BI_Form	Other
0060001	Kat_JaNein	Yes
0060002	Kat_JaNein	No

9996001	Kat_BI_Ventiltyp	Integrated (magnetic valve)
9996002	Kat_BI_Ventiltyp	Remote (with tube and port system)
0130001	KAT_BI_Hersteller	Allergan
0130002	KAT_BI_Hersteller	Cereplas
0130003	KAT_BI_Hersteller	CUI (Cox Uphoff Implants)
0130004	KAT_BI_Hersteller	EMSI Biomedical
0130005	KAT_BI_Hersteller	Establishment labs
0130006	KAT_BI_Hersteller	Eurosilicone
0130007	KAT_BI_Hersteller	Nagor
0130008	KAT_BI_Hersteller	Groupe Sebbin
0130009	KAT_BI_Hersteller	Laboratoires Arion
0130010	KAT_BI_Hersteller	MENTOR Deutschland GmbH
0130011	KAT_BI_Hersteller	Pérouse Plastie SAS
0130012	KAT_BI_Hersteller	PIP M-Implants
0130013	KAT_BI_Hersteller	Polytech Health & Aesthetics
0130014	KAT_BI_Hersteller	Silimed
0130015	KAT_BI_Hersteller	Surgitek
0130042	KAT_BI_Hersteller	Other
0068001	Kat_KennzeichenTyp	GTINUDI
0068002	Kat_KennzeichenTyp	Reference (REF)
0068003	Kat_KennzeichenTyp	Catalogue number
0068042	Kat_KennzeichenTyp	Other
P060101010 1	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, SALINE, WITH SMOOTH SURFACE
P060101010 2	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, SALINE, WITH TEXTURED SURFACE
P060101019 9	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, SALINE - OTHER
P060101020 1	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, MADE OF SILICONE, WITH SMOOTH SURFACE

P060101020 2	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, MADE OF SILICONE, WITH TEXTURED SURFACE
P060101029 9	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ROUND, MADE OF SILICONE - OTHER
P060102010 1	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, SALINE, WITH SMOOTH SURFACE
P060102010 2	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, SALINE, WITH TEX- TURED SURFACE
P060102019 9	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, SALINE - OTHER
P060102020 1	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, MADE OF SILI- CONE, WITH SMOOTH SURFACE
P060102020 2	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, MADE OF SILI- CONE, WITH TEXTURED SURFACE
P060102029 9	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, ANATOMICAL, MADE OF SILICONE - OTHER
P060199	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, STANDARD - OTHER
P060201	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, BECKER TYPE
P060299	Kat_EMDN_EU- DAMED	BREAST IMPLANTS, EXPANDER - OTHER
0191001	Kat_BI_ZubehoerTyp	Mesh
0191002	Kat_BI_ZubehoerTyp	ADM
0131001	Kat_BI_Zube- hoerHersteller	Allergan (Natrelle)
0131002	Kat_BI_Zube- hoerHersteller	ARTIA (Lifecell)
0131003	Kat_BI_Zube- hoerHersteller	Braxon (MBP)
0131004	Kat_BI_Zube- hoerHersteller	EGIS (MBP)
0131005	Kat_BI_Zube- hoerHersteller	Establishment labs (Motiva)
0131006	Kat_BI_Zube- hoerHersteller	GalaFLEX (Galatea)
0131007	Kat_BI_Zube- hoerHersteller	GC Aesthetics (Eurosilicone)

0131008	Kat_BI_Zube- hoerHersteller	MENTOR Deutschland GmbH
0131009	Kat_BI_Zube- hoerHersteller	Native (MBP)
0131010	Kat_BI_Zube- hoerHersteller	STRATTICE (Lifecell)
0131011	Kat_BI_Zube- hoerHersteller	SurgiMend (Integra)
0131012	Kat_BI_Zube- hoerHersteller	TIGR (Novus scientific)
0131042	Kat_BI_Zube- hoerHersteller	Other