APPROVAL

Role	Name	Function	Signature
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Review	Julien Finci	CTO	
Approval	Mauro Rinaldi	RAQM	

PURPOSE

This procedure describes the process of creation, review, approval, and translation of labeling at ASPIVIX SA. It is based on applicable regulatory requirements regarding labeling of medical devices, i.e., SOR/98-282, US FDA 21 CFR Part 801 and the European Medical device Regulation 2017 /745:

- To comply with the obligations related to the UDI system (Article 27)
- To comply with registration obligations (Article 29 & 31)
- To ensure that the device is accompanied by the information set out in Annex I Section 23 in an official Union language(s) determined by the European Member State in which the device is made available.

SCOPE

This procedure applies to the whole labeling of ASPIVIX SA devices and includes but is not limited to instructions for use, labels, and information on packaging and product (UDI).

RESPONSIBILITIES

Responsible for establishing, implementing and maintaining of this SOP is the Regulatory Affairs & Quality Manager.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A
Update UDI procedure+ translation procedure clarification	B
Correction of the minimum requirements for the translation company, i.e., ISO9001/ISO17100	C
Update of T-306-1 by the addition of the e-IFU according to the EU Regulation No. 2021/2226, and subsequent removal of T-306-3; addition of ISO 15223-1:2021, ISO 20417:2021 and 11607-1:2019	D

Clarification of company's translation requirements in section 2.6	E
Remove date from approval table. The procedure has been reviewed and is still applicable.	F

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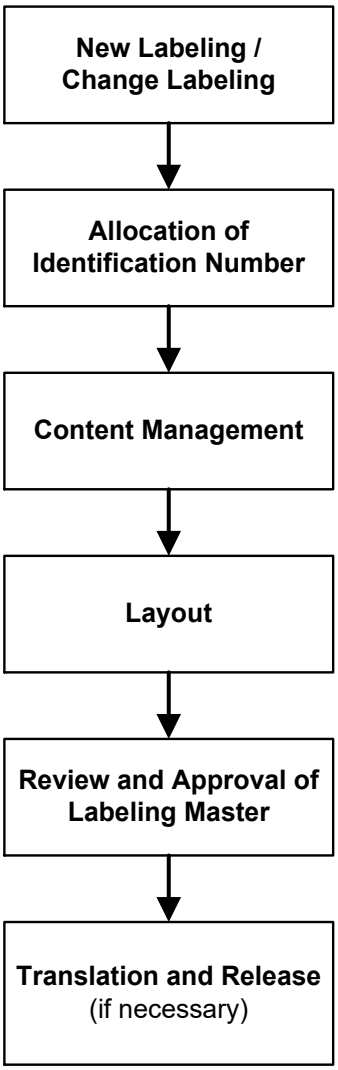
1 PROCEDURE FLOWCHART



2 PROCEDURE DESCRIPTION

2.1 NEW LABELING OR CHANGE

New labeling for new product is part of the Design & Development control, SOP-200 when labeling specifications have to be performed.

Changes of labeling will always be initiated with a change request as defined in SOP-303 Change Management. Only employee trained regarding change management can initiate a labeling change request if he/she sees a reason for it.

2.2 ALLOCATION OF IDENTIFICATION NUMBER TO LABELING

For new labeling as well as for changes of labeling, an allocation of a new identification number or a new version of an existing identification number respectively will be made to ensure traceability of the label, instructions for use, packaging or any other labeling.

Refer to Instruction Reference Attribution INS-203-1.

2.3 CONTENT MANAGEMENT

2.3.1 CONTENT REQUIREMENTS

Regarding content management, different people or departments might be involved. Editorial content from the authors such as internal employees (marketing, development, regulatory, quality, sales, complaint, etc.), customers, suppliers, doctors, key opinion leaders, distributors will be collected and coordinated.

Most of all, the following regulatory requirements as well as normative requirements have to be fulfilled:

- MDR 2017 /745
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied
- GHTF/SG1/N70:2011 Label and Instructions for Use for Medical Devices

In order to provide additional information to clinicians to help them to decide about the appropriateness of a given MR scan for a patient with an implant, a statement about image artifact produced by the item should be included in the product labeling. According to ASTM F2503, this concerns devices that are electrically operated (AC power or battery), that are known to contain metallic components or sub-components that may contain magnetic or electrically conductive materials (be aware that some items may contain metallic components that are not obvious (i.e. pillows, batteries), be also aware that some non-metallic materials (e.g. carbon fiber composites) are conductive and could pose an RF heating hazard) and all items that are intended to be placed within the MR imaging unit bore. The marking of these products should be done as described in ASTM F2503.

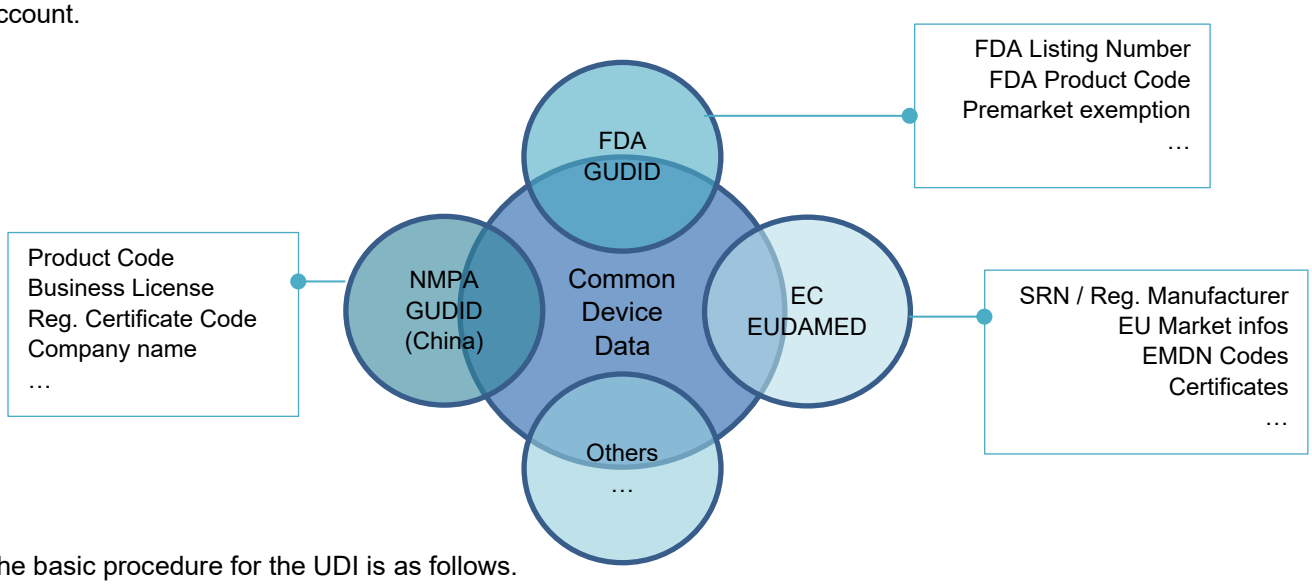
The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient.

As a tool for this process step, template T-306-1 Labeling Checklist shall be used.

2.3.2 UDI

Special focus in content management has to be paid to UDI.

Strategy for UDI management regarding the target markets and their relatives regulations need to be taken into account.



The basic procedure for the UDI is as follows.

2.3.3 UDI PROCEDURE FLOWCHART

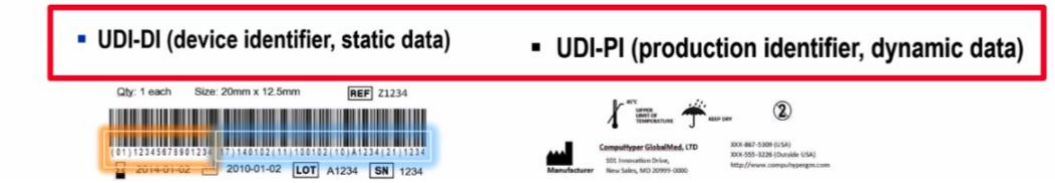
Note: The presence of the medical device UDI-DI on a device label does not mean that the medical device is authorized in all jurisdictions.

The data for new UDI-DI must be available at the time the medical device is placed on the market.

References: MDCG guidelines regarding UDI

Definition / Description of UDI:

UDI consists of a numeric/alphanumeric code



Specific to a manufacturer and a device	Identifies the produced device's unit like: Serial number Lot number Production date Expiration date Etc.

UDI must be placed on label of the device or on its packaging, but the basic UDI-DI not.

1. Assignment of UDI

All UDIs are to be issued under a system operated by an FDA- and EU-accredited issuing agency.

ASPIVIX SA has decided to use issuing agency GS1. For further information refer to the guidelines of issuing agency GS1.

The assignment of UDI-DI and basic UDI-DI to devices shall be done before submission for Class IIB & III to Notified Body for that assignment (article 28 & 29 – MDR).

2. Data entry for EUROPE Market

Registration of core UDI data elements in Eudamed.

Provide UDI-DI to the UDI database together with the other core data elements referred to in Part B of Annex VI related to that device.

3. Data entry for US Market

ASPIVIX SA uses the following submission option to fill in the GUDID Database:
There are two standards-based submission options:

- Structured input via the GUDID Web Interface – requires manual data entry and is geared for low volume submitters.
- Health Level 7 (HL7)8 Structured Product Labeling (SPL) submission via the FDA Electronic Submissions Gateway (ESG) – allows for submission via xml files and is geared for high volume submitters.

Prepare for GUDID (GUDID Checklist) – US Market
To fill the GUDID following information needs to be collected:

For each Device Identifier (DI) (no PIs):

- The proprietary/trade/brand name of the device,
- Previous DI if a new version or model
- The version or model number
- If direct marked, DI if different than label
- The size of the version or model
- The type of production identifiers on the label
- FDA premarket submission and listing number(s)

- Global Medical Device Nomenclature (GMDN) term (make sure that it is an active code)
- FDA product code (procode)
- The number of individual devices in each package.

Commercial distribution status:

- Higher levels of packaging
- Whether it is a kit; combination product; HCT/P

Whether the device is labeled:

- As sterile or sterilize before use (and how)
- As containing natural rubber latex,
- With MRI compatibility (safe, conditional, unsafe)

As Rx and/or OTC

4. Placing of UDI

Placement of UDI carries on devices / packaging.

Place the UDI in human readable and/or by automatic identification and data capture (AIDC) technology, such as a linear or 2D Data Matrix barcode on both the device (direct marking) and its label.

Direct Part Marking is a must to identify the device when it is no longer accompanied by its label or package. The UDI must be scannable for the whole life cycle of the product. The UDI should contain the DI and PI. The UDI requirements for the various packaging levels are still mandatory.

Recording of Basic UDI-DI in regulatory documents & for example on implant cards if any.

5. Storage, Maintenance & Changes of UDI

Storage

The economic operators shall store and keep the UDI (class III implants)

Maintenance

Maintenance is done by the quality manager.

All data relevant to the medical devices shall be reconfirmed periodically (to be included in the Management Review), except for discontinued medical devices. If a device is discontinued, the DI Record needs to be updated by entering a commercial distribution end date. There will be no deletion of a DI record.

The relevant UDI record must be updated within 30 days when a change is made to an element that does NOT require a new UDI-DI. The same timelines apply for general label updates (T-306-1 Labeling Checklist can be used to confirm the update).

Changes

Changes of UDIs are handled according to SOP-303 Change Management. Responsible is the quality manager.

A new DI is required in the following situations:

- Change of brand name
- A change to a device results in a new version or model (this would generally be a major change that the end user would notice such as a new component part, a new material, change to volume, length, gauge, diameter)
- Change to single use / non single use
- Change to sterile / non-sterile packaging
- Need for sterilization before use
- A new device package is created (new pack quantity or packaging solution)
- Critical warnings or contraindications change (e.g., containing Latex)
- Re-labelling of the original labeler's (manufacturer) device
- Change labelling languages for different global markets
- Change in certification mark (e.g., CE mark)

- At a minimum, a new UDI-DI is required whenever there is a change that could lead to misidentification of the medical device and/or ambiguity in its traceability

Any change that requires a new UDI will require a new entry into the database.
Changes should be updated within 15 days.

2.4 LAYOUT

2.4.1 PAPER FORM

The graphic design can be established either internally or externally. Important is the consideration of the corporate identity (CI) of ASPIVIX SA and the legal / regulatory requirements (e.g., size of CE mark) as well as applicable normative requirements. Use template T-306-1 Labeling Checklist to document compliance. For product labels it should be taken care that symbols are preferred to text. Furthermore, it must be ensured that the copyright stays with ASPIVIX SA and all data is sent electronically to ASPIVIX SA.

2.4.2 ELECTRONIC FORM (E-IFU)

The possibility of electronic instructions for use shall be used as it might be beneficial for professional users.

The use of electronic instructions for use is limited to certain medical devices and accessories and is subject to a specific risk assessment by the manufacturer. In any case, for reasons of safety and efficiency users always have the possibility to obtain instructions for use in paper form on request at no additional cost (EU Regulation No. 207/2012).

The requirements for the e-IFU are also included in the T-306-1.

2.5 REVIEW AND APPROVAL

Before the risk management report approval, the R&D technician or QA will initiate the review of the product labeling in compliance with the applicable requirements by drafting the template T-306-1 Labeling Checklist. The CTO and the Marketing & Sales Management will review and the Regulatory Affairs & Quality Manager will approve the T-306-1. Once it is approved, the template will be archived in Labeling Specifications folder of the DHF.

Before placing a device on the market, other than a custom-made device, ASPIVIX SA shall enter or if, already provided, verify in EUDAMED the information referred to in Section 2 of Part A of Annex VI, except for Section 2.2 thereof, and shall thereafter keep the information updated.

2.6 TRANSLATION

To ensure accurate translation of labels, IFUs, manuals, and other accompanying documents as well as product claims in marketing material, the following process and requirements must be respected:

These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation.

- At ASPIVIX SA, the language used for the labeling master is English.
- The translation can be performed internally or externally but it must be ensured that it is performed by qualified persons. When outsourced, the translation service provider must be selected and approved according to the SOP-305 Supplier handling. The minimum mandatory requirement shall be incompliance with the :
    - ISO17100 Translation services — Requirements for translation services
- Additionally, other requirements that are not mandatory, but are considered a plus are the following:
    - ISO 9001, Quality management systems — Requirements. A preference is given whether the quality management system of the service provider is certificated under this standard.
    - ISO 20771 Legal translation — Requirements; It is a plus when assessing the translation services provider.

- The labeling master will be translated into the requested language in which the product is commercialized.
  ASPIVIX SA shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient.
  This is defined for product in the record: Regulatory Product Requirement & pathway (T-200-8).
- The translated document will then be sent to the local distributor or affiliate for checking. Besides the language, the local representative also knows the product and can assess if the functional part was interpreted correctly.
- The document will be aligned between ASPIVIX SA and the local representative.
  Note:
  - Do not forget legal / regulatory requirements that might apply (e.g., address of local distributor on label etc.)
  - The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.
- After it has been agreed on a final version the representative has to fill in from T-306-2 Translation Confirmation and confirm that the translated version is equivalent to the labeling master. This confirmation must be archived at ASPIVIX SA.

3 REFERENCES

3.1 PROCEDURES, INSTRUCTIONS AND GUIDELINES

[1] SOP-303 Change Management
[2] SOP-305 Supplier Handling
[3] European Medical device Regulation MDR 2017 /745
[4] EN 1041: Information supplied by the manufacturer of medical devices
[5] GHTF/SG1/N70: Label and Instructions for Use for Medical Devices
[6] EN 1041 Information supplied by the manufacturer of medical devices
[7] EN ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
[8] ISO 20771Legal translation — Requirements
[9] ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
[10] US FDA 21 CFR Part 801 Labeling
[11] US FDA: Global Unique Device Identification Database (GUDID) – Guidance for Industry and Food and Drug Administration Staff http://www.fda.gov/udi
[12] US FDA: Unique Device Identification System https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system
[13] GUDID User Manual http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm
[14] EU Regulation No. 2021/2226– electronic instructions for use of medical devices
[15] EU MDCG 2018-1 Guidance on BASIC UDI-DI and changes to UDI-DI
[16] ISO 20417: Medical devices - Information to be supplied by the manufacturer
[17] ISO 11607 : Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging

3.2 TEMPLATES AND FORMS

[18] T-306-1 Labeling Checklist

[19] T-306-2 Translation Confirmation

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