Number: MKT-SOP-001
Version: C.3
Released: 15-Feb-2021

Name: Labeling Policy

Windchill Signature History Report			
Signature	**Role**	**Event Date**	**Vote**
Maullon, Robert Julius [NEUUS] (rmaullo)	Quality Operations	01-Feb-2021 15:32:30 EST	Approve
Horner, Shawn [ETHUS] (shorner2)	Research and Development	29-Jan-2021 17:28:36 EST	Approve

Megadyne Medical Products, Inc.	STANDARD OPERATING PROCEDURE	Document Number MKT-SOP-001
	Labeling Policy	Revision: C
		Page 1 of 5

1. PURPOSE

The purpose of this policy is to provide a general overview of labeling activities for the medical devices and accessories that Megadyne Medical Products, Inc. manufactures and/or distributes.

2. SCOPE

The scope of this policy applies to the labeling activities of products and accessories at Megadyne. Labeling activities include, but are not limited to, written, printed or graphic information that accompanies a product or is attached directly to a product or to any one of its packaging components related to the identification, technical description and/or use of the product.

3. REFERENCES

3.1. Standards and Regulations

- 21 CFR 801 Medical Device Labeling
- 21 CFR 820 Quality System Regulation
- 21 CFR 830 Unique Device Identification
- 93/42/EEC Medical Device Directive
- MDR 2017/745 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
- ISO 13485 Medical Devices, Quality Management Systems
- ISO 15223-1 Symbols to be used with Medical Device Labels
- SOR 92-282 Medical Device Regulations (Canada)
- MHLW no. 169 Ministerial Ordinance on Standards for Manufacturing Controls and Quality Control for Medical Devices and IVD Reagents (Japan)
- RDC 16/2013 Brazil ANVISA
- TGA, 2002 Australia Therapeutic Goods Medical Devices Regulations

3.2. Internal References

- RA-SOP-015 Labeling Content and Development Procedure
- RA-SOP-016 Translations Requirements Procedure
- 100494965 Franchise Procedure for Review and Approval of Advertising and Promotional Materials for MD (shared)
- RA-SOP-012 Document Management and Record Retention

Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.

- QA-SOP-013 PLM Change Control and Document Management Procedure
- OPER-WI-056 Operational Control of Product Labeling
- MKT-WI-001 Nomenclature Guidelines for Product Descriptions
- ENG-WI-031 UDI Label Requirements
- HR-SOP-001 Personnel Training and Qualification Procedure
- WE001516 Global Trade Identification Number Work Instruction

4. ROLES AND RESPONSIBILITIES

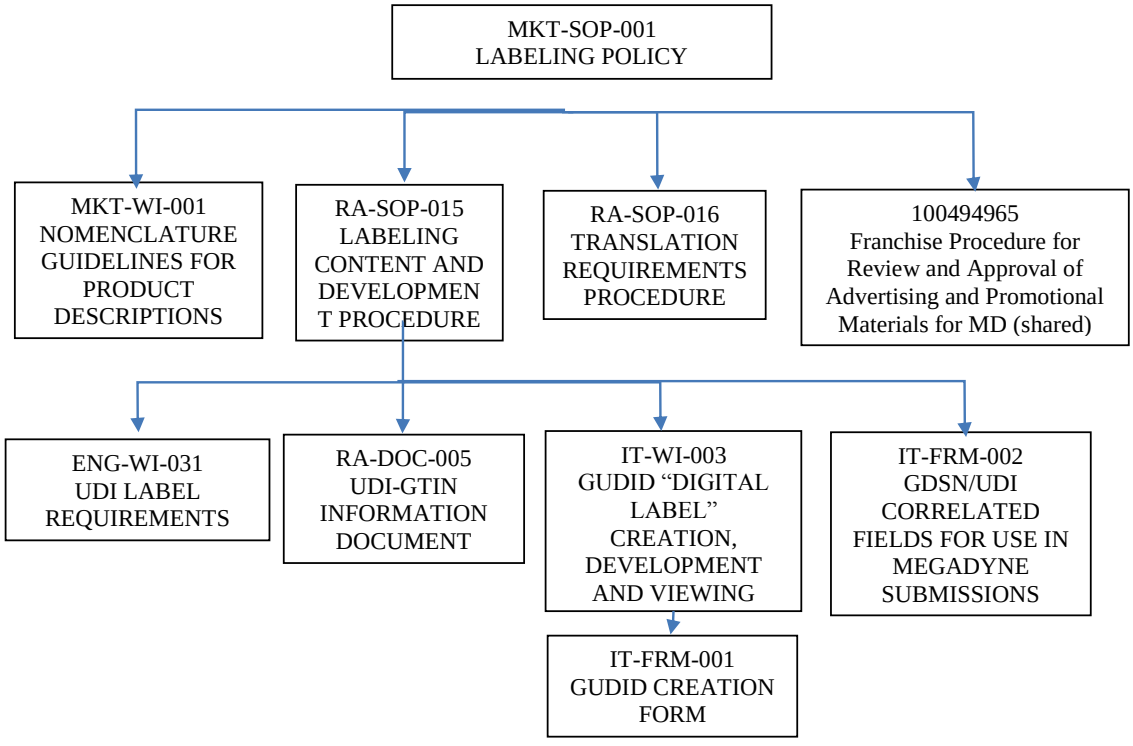
Role	Responsibility
Document Control	▪ Responsible for the change control process for labeling. ▪ Responsible for control of label and labeling master files and specifications.
Drafting	▪ Develop labeling artwork and drawings.
Engineering	▪ Ensure that labels, drawings, bills of material, user documents and service documents are technically accurate. ▪ Ensure risk information is adequately disclosed on applicable labels. ▪ Assures that label instructions and application requirements are properly communicated to production personnel through adequate written instructions, standard operating procedures, pictures, diagrams, etc.
Information Technology (IT)	▪ Manage GUDID account for designated Labelers. ▪ Manage day to day entry, submission and management of device identification information for designated Labeler DUNS.
Marketing	▪ Develop claims and indications for use statements. ▪ Ensure labeling is aligned with Megadyne branding. ▪ Identify target countries for each product and applicable language requirements. ▪ Ensures social media communication is aligned with Megadyne policy.
Medical Affairs	▪ Assist in the review of labels containing medical facts or claims to ensure the statements are referenced and accompanied by supporting documentation (data, chart, studies, etc.).
Production	▪ Ensure the label is correct, legible, and straight, and is placed in the proper location. ▪ Responsible for ensuring that labeling activities are documented in applicable records.
Purchasing	▪ Communicates between Megadyne and vendors, including translation service providers.
Quality Assurance	▪ Ensure that vendor labeling on finished goods supplied by vendors are in compliance with outlined Megadyne labeling requirements. ▪ Ensure that procedures, work instructions and specifications associated with the inspection and release of printed and digital materials are followed. ▪ Performs inspection of labeling on products to ensure it meets DMR requirements.

Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.

Megadyne Medical Products, Inc.	STANDARD OPERATING PROCEDURE	Document Number MKT-SOP-001
	Labeling Policy	Revision: C
		Page 3 of 5

Role	Responsibility
Regulatory Affairs	▪ Owns the overall labeling activities for Megadyne. ▪ Review labeling content to ensure compliance to applicable regulations and standards. ▪ Verify that claims and indications for use are consistent with regulatory submissions and filings. ▪ Ensure that claims are supported by valid scientific evidence when or if changing indications for use, contra-indications, or intended use. ▪ Ensure that products have the required language translations in accordance to applicable laws and regulations. ▪ Manage GUDID submission requirements for the Labelers in a given GUDID account.
Translation Service Provider	▪ 3rd Party service provider who assists with translations for Megadyne products and accessories.

5. LABELING PROCESS



Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.

Megadyne Medical Products, Inc.	STANDARD OPERATING PROCEDURE	Document Number MKT-SOP-001
	Labeling Policy	Revision: C
		Page 4 of 5

6. LABELING CROSS REFERENCE TABLE

Labeling Activity	Document Name / Number
Labeling Overview	Labeling Policy (MKT-SOP-001)
Labeling Control	PLM Change Control and Document Management Procedure (QA-SOP-013) Operational Control of Product Labeling (OPER-WI-056) Document Management and Record Retention (RA-SOP-012)
Labeling Content, Development and Symbols	Labeling Content and Development Procedure (RA-SOP-015) GTIN Issued Numbers (WE001516)
UDI Labeling	UDI Label Requirements (ENG-WI-031)
Translations	Translations Requirements Procedure (RA-SOP-016)
Nomenclature	Nomenclature Guidelines for Product Descriptions (MKT-WI-001)
Advertising and Promotional Materials	Franchise Procedure for Review and Approval of Advertising and Promotional Materials for MD (shared) (100494965)
Social Media	Franchise Procedure for Review and Approval of Advertising and Promotional Materials for MD (shared) (100494965)
Quality System Records	Document Management and Record Retention (RA-SOP-012)
Training	Personnel Training and Qualification Procedure (HR-SOP-001)

7. GENERAL REQUIREMENTS

7.1. Labeling Control

7.1.1. Labeling activities shall be controlled by standard operating procedures and work instructions to ensure appropriate labeling, packaging, handling, storage and distribution.

7.1.2. The requirements to control labels and labeling activities have been established throughout the various labeling procedures and work instructions identified in the Labeling Cross Reference Table in this procedure.

7.1.3. Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling and distribution.

7.2. Labeling Content, Development and Symbols

7.2.1. The content and development of labeling is performed by multiple departments at Megadyne who have specific responsibilities related to their areas of expertise.

Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.

7.2.2. The labeling content and development requirements are defined in the Labeling Content and Development Procedure (RA-SOP-015).

7.2.3. The development of a GTIN number is outlined in RA-SOP-015 with the defined/created GTIN controlled within WE001516.

7.2.4. Commonly used symbols are outlined in RA-SOP-015.

7.3. Translations

7.3.1. Labeling requiring translations into a language other than English shall follow the requirements identified in the Labeling Translations Requirements Procedure (RA-SOP-016).

7.4. Advertising and Promotional Material

7.4.1. The content of advertisements, press releases and promotional materials is reviewed and approved before release.

7.4.2. The requirements for the use of advertising and promotional materials are defined in the Franchise Procedure for Review and Approval of Advertising and Promotional Materials for MD (shared) (100494965).

7.5. Quality Records

7.5.1. Travelers, forms and/or documents used in operations to capture data from labeling are considered quality records.

7.5.2. The requirements for maintaining quality records are described in the Document Management and Record Retention Procedure (RA-SOP-012).

7.6. Training Documentation

7.6.1. Training is assigned to employees performing labeling activities to ensure they are competent to perform the procedures and work instructions applicable to their roles and responsibilities.

7.6.2. The process describing the assigning of training and the maintenance of training records is described in the Personnel Training and Qualification Procedure (HR-SOP-001).

8. REVISION HISTORY

REV	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
Refer to PLM system for subsequent revisions			

Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.