Promoting Certified Status and MDSAP Participation, Using Marks and Logos

Legal Scope:

TÜV Rheinland of North America Inc.

Business Scope:

P.05 Medical

Process Scope:

6.3 Service Delivery : 6.3.3 Certification

1. Objectives

The purpose of this guideline is to describe the applicability and use of the below listed marks and logos, as well of the promotion of certified status or MDSAP participation by organizations (furthermore called certification holder and MDSAP participant respectively) certified or audited by TUV Rheinland of North America, Inc. (TRNA).

2. Terms and Abbreviations

Terms/Abbreviations	Description
Accompanying information	considered as separately available or easily detachable. Note: Type labels or identification plates are considered as part of the product
CMDCAS	Canadian Medical Devices Conformity Assessment System
Mark	the logo, symbol, or other graphic representation that identifies the CB, AO or AB
MDSAP	Medical Devices Single Audit Program
Product packaging	considered as that which can be removed without the product disintegrating or being damaged

3. Scope of Application

The requirements herein are applicable only to organizations certified or audited by TRNA.

Note: for certifications where TÜV Rheinland LGA Products GmbH (TRLP) is the accreditation holder or designated Notified Body, different rules may apply. To learn more about TRLP test marks and their use, visit:

Overview | blueye (tuv.group)

4. Activities

4.1 General requirements

The certification holder or MDSAP participant shall:

a) conform to the requirements of TRNA when making reference to its certification status or MDSAP participation in communication media such as the internet, brochures or advertising, or other documents,

b) not make or permit any misleading statement regarding its certification or MDSAP participation,

c) not use or permit the use of a certification document, MDSAP audit report or any part thereof in a misleading manner,

d) upon suspension or withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification, as directed by TRNA,

e) amend all advertising matter when the scope of certification has been reduced,

f) not allow reference to its management system certification or MDSAP participation to be used in such a way as to imply that the certification body certifies a product (including service) or process,

g) not imply that the certification or MDSAP participation applies to activities that are outside the scope of certification, and

h) not use its certification or MDSAP participation in such a manner that would bring TRNA and/or the certification system(s) into disrepute and lose public trust.

For multiple site organizations, the claim to the certified status or MDSAP participation shall only be used in conjunction with the organization's name and facility that is covered in the scope of certification or audit.

For a certificate holder or MDSAP participant that gained certification or was audited for only a portion of their processes, products or services, claims of certification or MDSAP participation must be specific and not provide the impression of "organization-wide" certification or participation.

The claim to the certified status or MDSAP participation may not be used for the labeling of individual products or evidence of service provision, or in intimate association with the products or services in a manner that suggests that the products or services themselves are certified / registered / endorsed by TRNA. The claim to the certified status or MDSAP participation shall not be used on test, calibration or inspection reports.

It is permitted to state on the Product packaging or in Accompanying information that the certification holder has a certified QMS. The statement shall in no way imply that the product, process or service is certified by this means. The statement shall include reference to:

- identification (e.g. brand or name) of the certified client;
- the type of management system (e.g. quality, environment) and the applicable standard;
- the certification body issuing the certificate (see spelling of TRNA below).

The certificate holder or MDSAP participant is responsible to TRNA for the claim to the certified status or MDSAP participation, ensuring that its use in advertising or other activities takes place within these conditions. In cases of doubt, the certificate holder or MDSAP participation shall contact TRNA for clarification.

The use of the claim to the certified status or MDSAP participation is limited to legal persons and must not, without the express permission of TRNA, be transferred to third parties or successors or be the subject of an assignment or a sale or of any sort of enforced measure.

If necessary, other requirements with regard to the use of claim to the certified status or MDSAP participation will be developed between the individual certificate holders or MDSAP participants and TRNA. Such requirements will be part of the certification / service agreement and the certificate holder or MDSAP participant will immediately be subject to such requirements.

The certificate holder or MDSAP participant is also responsible to TRNA for any promotion of its certified status or MDSAP participation by others on its behalf over which it has control or influence (e.g., corporate headquarters) by ensuring that such promotion in advertising or other activities takes place in accordance with the conditions specified within this document.

The certificate holder or MDSAP participant is responsible for following these rules and guidelines, and their correct use will be verified by TRNA during audit activities.

4.2 Particular requirements

4.2.1 Stating the certified status in text

Holders of valid (not draft, suspended, expired or withdrawn) certification may refer to their certified status using the following (or similar) general text syntaxes:

Certified to [QMS standard with issue date] by TUV Rheinland of North America, Inc.

[QMS standard with issue date] certified by TUV Rheinland of North America, Inc.

[QMS standard with issue date] certification by TUV Rheinland of North America, Inc.

etc., where [QMS standard with issue date] is the full reference to the certification criteria, such as ISO 9001:2015, ISO 13485:2016, ISO 13485:2016 under MDSAP.

4.2.2 Reference to the name of TRNA

When referring to the CB or AO in the context of a claim to certified status, instead of the abbreviation TRNA, use the full name: TUV Rheinland of North America, Inc.

Note: TRNA has no umlaut (Ü) in the official registration.

Apart from in the trademark, TUV Rheinland should always be written as two words. A space should always be put between the two parts of the name, TUV and Rheinland. These two constituent parts should never be separated by a line break or anything similar.

In running text, TUV should never be emphasized by using a semi-bold font weight.

The brand name TUV Rheinland never takes an article. For example, please never use "the TUV Rheinland..." This applies to all kinds of texts, e.g., advertisements, brochures and press releases.

4.2.3 Conditions for using the TÜV Rheinland Certified Mark

The use of the TÜV Rheinland Certified Mark is currently not available for the certification schemes provided by TRNA.

If as certification holder you wish to request the expansion of the TÜV Rheinland Certified Mark to the scheme that your QMS is certified to, please use the Contact button in the above web page.

4.2.4 Conditions for using the TÜV Rheinland trademark

The TÜV Rheinland logo is protected, among others, by the European trademark registered for TÜV Rheinland AG, Reg.-No. 005871116.

The use of the trademark of TÜV Rheinland is subject to a License Agreement and Guideline (CD Guideline Appendix 1).

The trademark may not be used as a test or certification mark.

4.2.5 Use of ISO name and logo

In general, certification holders may not use the name or logo of ISO to refer to their certified status, including the terms "ISO certified" or "ISO certification".

Further information: https://www.iso.org/iso-name-and-logo.html

4.2.6 Conditions for using accreditation marks

At this time, there are no approvals for the use of any accreditation marks, including that of the Standards Council of Canada (SCC).

4.2.7 Conditions for referring to MDSAP certified status or MDSAP participation

Additionally to all applicable General and Particular requirements of this Guideline, the scope of MDSAP certification also means the applied regulatory documents. The general terms “ISO 13485:2016 under MDSAP” imply these applied regulatory documents and thus they do not need to be additionally mentioned.

Organizations with one or more facilities participating in MDSAP (bearing MDSAP audit reports with positive recommendations) who are not eligible for MDSAP certification, may refer to their participation in MDSAP in the following (or similar) forms:

<u>If all facilities within the QMS participate in MDSAP:</u>

[Organization name] participating in MDSAP

[Organization name] audited to ISO 13485:2016 under MDSAP by TUV Rheinland of North America, Inc.

<u>If not all facilities of the QMS participate in MDSAP:</u>

[Facility XYZ] of [Organization name] participating in MDSAP,

[Facility XYZ] of [Organization name] audited to ISO 13485:2016 under MDSAP by TUV Rheinland of North America, Inc.

If multiple facilities are in a campus, reference to the main address of the campus (as in the MDSAP audit report) is sufficient, but the included facilities may also be individually referred.

4.2.8 Conditions for referring to using the MDSAP logo

The MDSAP logo (not provided by TRNA) may be used when referring to the MDSAP certified status or MDSAP participation, subject to all applicable General and Particular requirements of this Guideline.

5. Roles & Responsibilities

The certification holder or MDSAP participant is responsible for implementing the requirements of this guideline when promoting its certified status.

6. Specifications

N/A

7. Attachments

N/A

8. Related Documents

MS-0005820 - Critical Location Agreement

9. External Reference Documents

N/A