CGA M-23—2019

STANDARD FOR REGULATORY CLASSIFICATION OF MEDICAL DEVICE GASES

FIRST EDITION

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1 Introduction

Medical device gases are a unique intersection of medical gases and medical devices. A consistent and uniform industry-wide classification system is needed to address these medical device gases.

In the United States, medical device gases are often improperly classified with the Food and Drug Administration (FDA) based on the classification of the device they support. Some of these device gases include gases that have historically required FDA 510(k) premarket authorization (e.g., lung diffusion mixtures). Examples of improper classification include, anaerobic and aerobic mixtures classified under “glove boxes” and “water bath” because the gases are used with these devices.

In Canada, some gases listed in this publication are considered drugs by Health Canada. Medical gases are classified as medical devices if they meet the definition of a medical device per the *Food and Drugs Act* [1].[1]

The improper classification could cause additional regulatory problems including compliance with Unique Device Identification (UDI) requirements. The medical gas industry’s standards require that device gases have traceable lot numbers and that cylinders and valves are identified by their manufacturer. In combination cylinders with valves intended to house a medical gas drug or medical device gas are regulated as container closure systems.

2 Scope and purpose

2.1 Scope

This publication provides clarification on the regulatory classification of medical device gas mixtures.

2.2 Purpose

This publication will assist in meeting existing FDA and Health Canada requirements on device gas classifications by providing the industry with clarity on the classification of medical device gases to ensure uniform registration and listing across the industry [2, 1].

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall
Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should
Indicates that a procedure is recommended.

3.1.3 May
Indicates that the procedure is optional.

3.1.4 Will
Is used only to indicate the future, not a degree of requirement.

3.1.5 Can
Indicates a possibility or ability.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.