CGA

Compressed Gas Association

The Standard For Safety Since 1913

# CGA M-20—2020

## GUIDELINE FOR THE IMPLEMENTATION OF UNIQUE DEVICE IDENTIFICATION

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

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# 1 Introduction

On September 24, 2013, the Food and Drug Administration (FDA) published the Unique Device Identification (UDI) final rule under Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 830, and subsequently issued Global Unique Device Identification Database (GUDID) guidance on June 26, 2014 [1, 2][1]. This publication describes the CGA position of manufacturers, distributors, and specification developers of medical devices used in the medical gas and gas equipment industry regarding 21 CFR Part 830 and associated guidance [1, 2]. It describes the industry's interpretation and application of the requirements for the creation and maintenance of UDIs and the submission of the related database records in electronic format. This publication should be utilized to create a firm's standard operating procedures (SOP) for compliance with the regulation.

FDA has identified the effective dates of required implementation for various aspects of the final rule. Companies affected by this rule are required to satisfy labeling requirements based upon the classification of their device, if it is considered life supporting or life sustaining, or if it is a reusable device that requires processing between use. This publication clarifies the interpretation of these requirements as they relate to associated products within the compressed gas industry.

# 2 Scope

This publication applies to manufacturers, distributors, and specification developers of medical devices used in the medical gas and gas equipment industry.

This publication does not apply to the manufacturing, reprocessing, and requalifying of cylinders or plain cylinder valves or the combining of the two because they are not classified as medical devices.

This publication is based upon:

- 21 CFR Part 830 [1];
- FDA's GUDID guidance [2]; and
- CGA PS-53, *Position Statement on Pressure Regulators, Cylinder Valves, and Cylinders with Valves as Medical Devices* [3].

# 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.