CGA M-20—2017

GUIDELINE FOR THE IMPLEMENTATION OF UNIQUE DEVICE IDENTIFICATION

FIRST EDITION

CGA
Compressed Gas Association
The Standard For Safety Since 1913

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Contents **Page**

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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]. This publication describes the industry position of both manufacturers and distributors 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 device barcodes 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 each of these milestones based upon the classification of their device, if it is already on the market as of a specific date and labeled, if it is considered life supporting or life sustaining per FDA's definition, 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 is based upon:

- 21 CFR Part 830 [1];
- FDA's GUDID guidance [2]; and
- Compressed Gas Association's (CGA) letters to FDA regarding these issues dated November 1, 2012 and July 8, 2014 [3, 4].

2.1 Product codes included

This publication covers the following product codes and their associated descriptions.

Product code	Classification	21 CFR section	Description
CAW	Class II	866.5440	Generator, oxygen, portable (includes both stationary and portable)
NFB	Class II	868.5905	Conserver, oxygen
BYJ	Class II	868.5655	Unit, liquid oxygen portable (includes both base and portable units)
BYX	Class I	868.5860	Pressure tubing and accessories
ECX	Class 1	868.2700	Cylinder, compressed gas and valve (VIPR only)
CAN	Class I	868.2700	Regulator, pressure, gas cylinder (includes some stand-alone VIPRs)
CAX	Class I	868.2340	Flowmeter, tube, THORPE, back-pressure compensated
CCN	Class I	868.2300	Flowmeter, nonback-pressure compensated, bourdon gauge
BXO	Class I	868.2900	Gas pressure transducer
CAM	Class I	868.6885	Medical yoke
KZJ	Class I	866.2580	Device, gas generating

This publication does not include guidance for implementation of UDI for standalone software. See 21 CFR Part 801 for guidance for standalone software [1].