



**CGA M-20—2020  
GUIDELINE FOR THE  
IMPLEMENTATION OF UNIQUE  
DEVICE IDENTIFICATION**

**SECOND EDITION**

Currently in preview, click buy full version

**PLEASE NOTE:**

The information contained in this document was obtained from sources believed to be reliable and is based on technical information and experience currently available from members of the Compressed Gas Association, Inc. and others. However, the Association or its members, jointly or severally, make no guarantee of the results and assume no liability or responsibility in connection with the information or suggestions herein contained. Moreover, it should not be assumed that every acceptable commodity grade, test or safety procedure or method, precaution, equipment or device is contained within, or that abnormal or unusual circumstances may not warrant or suggest further requirements or additional procedure.

This document is subject to periodic review, and users are cautioned to obtain the latest edition. The Association invites comments and suggestions for consideration. In connection with such review, any such comments or suggestions will be fully reviewed by the Association after giving the party, upon request, a reasonable opportunity to be heard. Proposed changes may be submitted via the Internet at our web site, [www.cganet.com](http://www.cganet.com).

This document should not be confused with federal, state, provincial, or municipal specifications or regulations; insurance requirements; or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding unless adopted by reference in regulations.

A listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available via the Internet at our website at [www.cganet.com](http://www.cganet.com). For more information contact CGA. Phone: 703-788-2700, ext. 799. E-mail: [customerservice@cganet.com](mailto:customerservice@cganet.com).

Work Item 22-003  
Medical Equipment Committee

NOTE—Technical changes from the previous edition are underlined

SECOND EDITION: 2020

FIRST EDITION: 2017

© 2020 The Compressed Gas Association, Inc. All rights reserved.

All materials contained in this work are protected by United States and international copyright laws. No part of this work may be reproduced or transmitted in any form or by any means, electronic or mechanical including photocopying, recording, or any information storage and retrieval system without permission in writing from The Compressed Gas Association, Inc. All requests for permission to reproduce material from this work should be directed to The Compressed Gas Association, Inc., 8484 Westpark Drive, Suite 220, McLean VA 22102. You may not alter or remove any trademark, copyright or other notice from this work.

<b>Contents</b>	<b>Page</b>
1 Introduction.....	1
2 Scope .....	1
3 Definitions.....	1
4 Purpose of unique device identification and Global Unique Device Identification Database requirements ...	2
5 Implications of the unique device identification regulations for medical devices.....	3
5.1 Classification .....	3
5.2 Exception for existing manufactured and labeled devices.....	3
5.3 Life supporting or life sustaining medical gas equipment.....	3
5.4 Reprocessed between use.....	3
6 Compliance dates.....	3
7 Technical guidance for unique device identification.....	4
7.1 Medical gas equipment requiring unique device identification .....	4
7.2 Medical gas and medical gas equipment not requiring a unique device identification .....	4
7.3 Labeler responsibilities.....	5
7.4 Device distributor responsibilities .....	5
8 References .....	5
<b>Tables</b>	
Table 1—Compliance dates by device class .....	3
Table 2—Devices requiring unique device identification.....	4
Table 3—Devices not requiring UDI.....	5

## 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]<sup>1</sup>. 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.

---

<sup>1</sup> References are shown by bracketed numbers and are listed in order of appearance in the reference section.