American National Standard

ANSI/AAMI/ UL 2800-1-3: 2022

Standard for Interoperable Item Integration Life Cycle



This is a preview. Click here to purchase the full publication.

American National Standard

Standard for Interoperable Item Integration Life Cycle

Approved 20 May 2022 by **AAMI**

Approved 10 June 2022 by American National Standards Institute, Inc.

Abstract: Specifies a baseline set of requirements for assuring safe and secure interoperability for Interoperable Medical Systems.

Keywords: interoperability requirements, medical systems, medical devices, interoperable systems

This is a preview. Click here to purchase the full publication.

Commitment for Amendments

This Standard is issued jointly by the Association for the Advancement of Medical Instrumentation (AAMI) and Underwriters Laboratories Inc. (UL). Comments or proposals for revisions or any part of the standard may be submitted to AAMI and/or UL at any time. Revisions to this Standard will be made only after processing according to the Standards development procedures of AAMI and UL.

Published by

AAMI 901 N. Glebe Road, Suite 300 Arlington, VA 22203 www.aami.org

© 2022 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact the Copyright Clearance Center.

Copyright © 2022 Underwriters Laboratories Inc.

UL's Standards for Safety are copyrighted by UL. Neither a printed nor electronic copy of a Standard should be altered in any way. All of UL's Standards and all copyrights, ownerships, and rights regarding those Standards shall remain the sole and exclusive property of UL.

This ANSI/UL Standard for Safety consists of the Second Edition. The most recent designation of ANSI/UL 2800-1 as an American National Standard (ANSI) occurred on February 25, 2019. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page (front and back), or the Preface.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at https://csds.ul.com.

To purchase UL Standards, visit UL's Standards Sales site at <u>http://www.shopulstandards.com/HowToOrder.aspx</u> or call toll-free 1-888-853-3503.

Printed in the United States of America

ISBN 978-1-57020-846-1

This is a preview. Click here to purchase the full publication.

Contents

Committee representation iv AAMI Standard v Standard for Interoperable Item Integration Life Cycle 1 1 Introduction 1 2 Scope 2 3 Referenced Publications 2 4 Terms and Definitions 3 5 Interoperable Item Integration Life-Cycle Activities 3 Annex A (Informative) Architecture Definition Guidance 13 Annex B (Informative) Interoperability Architecture Specification 24

This is a preview. Click here to purchase the full publication.

Page