

American
National
Standard



ANSI/AAMI HIT1000-1: 2022

Safety and effectiveness
of health IT software
and systems—Part 1:
Fundamental concepts,
principles, and
requirements

Safety and effectiveness of health IT software and systems—Part 1: Fundamental concepts, principles, and requirements

Approved 25 January 2022 by
AAMI

Approved 01 March 2022 by
American National Standards Institute, Inc.

Abstract: Identifies the fundamental concepts and principles for creating, integrating, and implementing health IT software and health IT systems to maintain safety and effectiveness.

Keywords: health software, health IT, quality, quality systems, risk, risk management, usability, human factors engineering, safety, effectiveness, security, assurance case, safety assurance case, health IT system, sociotechnical system

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Published by

AAMI
901 N. Glebe Road, Suite. 300
Arlington, VA 22203-1853
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-840-9

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