
**Health informatics — Personalized
digital health — Digital therapeutics
health software systems**

*Informatique de santé — Santé numérique personnalisée — Systèmes
logiciels de santé pour la thérapie numérique*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Context	5
5 Considerations	6
5.1 DTx Attributes.....	6
5.2 Impact on patient care.....	6
5.3 Relationship to SiMD.....	6
5.4 DTx in context of a DTx System.....	7
6 DTx in relation to ecosystem constructs	8
6.1 Existing ecosystem constructs.....	8
6.2 Medical device.....	9
6.3 Software as a Medical Device (SaMD).....	9
6.4 Software in a Medical Device (SiMD).....	10
6.5 Digital Health Technology (DHT) Frameworks.....	10
6.5.1 DHT Overview.....	10
6.5.2 Digital Therapeutics Alliance (DTA).....	10
6.5.3 National Institute for Health and Care Excellence (NICE).....	11
6.5.4 European Commission DG communications networks, content, and technology.....	12
7 Medical device software standards	13
Annex A (informative) Landscape analysis	14
Annex B (informative) DTx use cases	15
Bibliography	19