

# ISO/TR 11147:2023-06 (E)

## Health informatics - Personalized digital health - Digital therapeutics health software systems

---

<b>Contents</b>		<b>Page</b>
Foreword.....		iv
Introduction.....		v
<b>1</b>	<b>Scope.....</b>	<b>1</b>
<b>2</b>	<b>Normative references.....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions.....</b>	<b>1</b>
<b>4</b>	<b>Context.....</b>	<b>5</b>
<b>5</b>	<b>Considerations.....</b>	<b>6</b>
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
<b>6</b>	<b>DTx in relation to ecosystem constructs.....</b>	<b>8</b>
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
<b>7</b>	<b>Medical device software standards.....</b>	<b>13</b>
<b>Annex A (informative) Landscape analysis.....</b>		<b>14</b>
<b>Annex B (informative) DTx use cases.....</b>		<b>15</b>
<b>Bibliography.....</b>		<b>19</b>