

# DIN CEN ISO/TS 20451:2018-11 (E)

Health informatics - Identification of medicinal products - Implementation guidelines for ISO 11616 data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/TS 20451:2017); English version CEN ISO/TS 20451:2018

---

<b>Contents</b>		<b>Page</b>
	<b>Foreword</b> .....	<b>v</b>
	<b>Introduction</b> .....	<b>vi</b>
<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>2</b>
<b>4</b>	<b>Conformance</b> .....	<b>2</b>
<b>5</b>	<b>Concepts required for the unique identification of pharmaceutical products</b> .....	<b>2</b>
5.1	General considerations for elements required for the unique identification of pharmaceutical products.....	2
5.2	Principles required for the unique identification of a pharmaceutical product.....	2
<b>6</b>	<b>Identifying characteristics for the identification of pharmaceutical products</b> .....	<b>3</b>
6.1	Pharmaceutical product identification strata and levels.....	3
6.2	PhPID specified substance.....	4
6.3	Pharmaceutical product specified substance identification (PhPID SpSub).....	5
6.4	Cardinality.....	5
6.5	Representation of strength concentration.....	6
6.6	Pharmaceutical product identifier (PhPID).....	6
6.7	PhPID algorithm and product code concept.....	7
<b>7</b>	<b>Ingredient, substance and strength</b> .....	<b>8</b>
7.1	General considerations.....	8
7.2	Ingredient.....	9
7.2.1	Ingredient role.....	9
7.2.2	Substance.....	10
7.2.3	Specified substance.....	10
7.2.4	Specified substance group.....	10
7.2.5	Confidentiality indicator.....	11
7.2.6	Strength.....	11
7.2.7	Pharmaceutical product code concept for representing the normalised strength for liquid preparations.....	11
7.2.8	Strength (presentation).....	12
7.2.9	Strength (concentration).....	12
7.2.10	Measurement point.....	13
7.2.11	Country.....	13
7.2.12	Reference strength.....	13
7.2.13	Reference substance.....	13
7.2.14	Reference specified substance.....	13
7.2.15	Reference strength.....	13
7.2.16	Reference strength measurement point.....	14
7.2.17	Reference strength country.....	14
<b>8</b>	<b>Pharmaceutical product: adjuvants and devices</b> .....	<b>14</b>
8.1	General considerations.....	14
8.1.1	Detailed description of pharmaceutical product and device information.....	14
8.1.2	Pharmaceutical product.....	15
8.1.3	Pharmaceutical product characteristics.....	17
8.1.4	Device (pharmaceutical product).....	18

<b>Annex A (normative) Messaging: Ingredient, substance and strength</b> .....	<b>19</b>
<b>Annex B (normative) Messaging: Pharmaceutical product and device</b> .....	<b>33</b>
<b>Annex C (informative) Examples</b> .....	<b>40</b>
<b>Annex D (informative) Examples of representation of strength</b> .....	<b>45</b>
<b>Bibliography</b> .....	<b>48</b>