

# ISO 20417:2026-03 (E)

## Medical devices - Information to be supplied by the manufacturer

---

<b>Contents</b>		<b>Page</b>
Foreword		v
Introduction		vi
<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>General considerations</b>	<b>12</b>
<b>5</b>	<b>Information elements to be established</b>	<b>13</b>
5.1	Units of measurement	13
5.2	Graphical information	13
5.3	Language and country identifiers	14
5.3.1	Language identifiers	14
5.3.2	Country identifiers	14
5.4	Dates	14
5.5	Full address	14
5.6	<i>Model number</i>	15
5.7	<i>Catalogue number</i>	15
5.8	Production control identifiers	15
5.9	Unique device identifier	15
5.10	Types of use/reuse	16
5.11	<i>Sterile</i>	16
<b>6</b>	<b>Requirements for <i>accompanying information</i></b>	<b>16</b>
6.1	Requirements for information to be supplied on the <i>label</i>	16
6.1.1	Minimum requirements for the <i>label</i>	16
6.1.2	Identification of the <i>manufacturer</i>	17
6.1.3	Identification of the <i>medical device</i> or <i>accessory</i>	17
6.1.4	Other <i>label</i> requirements	20
6.1.5	Consult <i>instructions for use</i>	21
6.1.6	<i>Safety signs</i>	21
6.2	Identification requirements for detachable components of a <i>medical device</i> or <i>accessory</i>	22
6.3	Legibility of the <i>label</i>	23
6.4	Durability of <i>markings</i>	23
6.5	Information to be provided on the packaging	23
6.5.1	General information	23
6.5.2	Packaging for the <i>lay user</i>	25
6.5.3	Special conditions indicated on the packaging	25
6.5.4	<i>Sterile</i> packaging	26
6.6	Requirements for information in the <i>instructions for use</i> and <i>technical description</i>	27
6.6.1	General	27
6.6.2	Requirements for <i>instructions for use</i>	28
6.6.3	Additional requirements for the <i>instructions for use</i> for a <i>lay user</i>	33
6.6.4	Requirements for <i>technical description</i>	33
6.6.5	Requirements for <i>e-documentation</i>	36
<b>7</b>	<b>Other information that is required to be supplied with the <i>medical device</i> or <i>accessory</i></b>	<b>36</b>
7.1	<i>Importer</i>	36
7.2	<i>Distributor</i>	37
7.3	Repackaging	37
7.4	Translation	37
7.5	Regulatory identification	38

<b>Annex A (informative) Particular guidance and rationale</b> .....	<b>39</b>
<b>Annex B (informative) Example test method for assessing <i>clearly legible</i> requirements</b> .....	<b>41</b>
<b>Annex C (informative) Example test method for assessing durability</b> .....	<b>42</b>
<b>Annex D (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidance</b> .....	<b>43</b>
<b>Annex E (informative) Alphabetized index of defined terms</b> .....	<b>47</b>
<b>Bibliography</b> .....	<b>50</b>