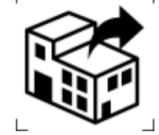
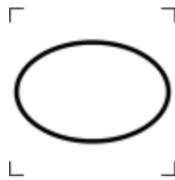
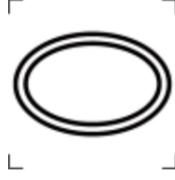
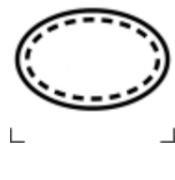
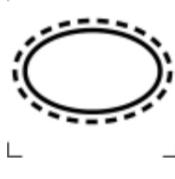


<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/ndbfa9256193f2b5f#ndbfa9256193f2b5f>

<p>5.1.8.</p> 	<p><i>Importer</i></p>	<p>Indicates the entity importing the <i>medical device</i> into the locale</p>	<p>This <i>symbol</i> shall be accompanied by the name and address of the importing entity, adjacent to the <i>symbol</i></p>	<p>NOTE If multiple <i>symbol</i> s (i.e., Authorized Representative, <i>Importer</i>, <i>Distributor</i>, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.</p>	
<p>5.1.9.</p> 	<p><i>Distributor</i></p>	<p>Indicates the entity distributing the <i>medical device</i> into the locale</p>	<p>This <i>symbol</i> shall be accompanied by the name and address of the distributing entity adjacent to the <i>symbol</i></p>	<p>NOTE If multiple <i>symbol</i> s (i.e., Authorized Representative, <i>Importer</i>, <i>Distributor</i>, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.</p>	
<p>5.1.10.</p> 	<p>Model number</p>	<p>To identify the model number or type number of a product</p>	<p>This <i>symbol</i> shall be accompanied by the model number of the product, adjacent to the <i>symbol</i>.</p>		
<p>5.1.11.</p> 	<p>Country of manufacture</p>	<p>To identify the country of manufacture of products</p>	<p>In the application of this <i>symbol</i>, the "CC" shall be replaced by either the two letter country code or the three letter country code defined in ISO 3166-1. The date of manufacture may be added adjacent to this <i>symbol</i>.</p>	<p>NOTE Not all authorities with jurisdiction recognize the two letter or three letter country codes found in ISO 3166-1.</p>	<p>The use of this <i>symbol</i> with a date of manufacture precludes the use of <i>symbol</i> 5.1.3</p>

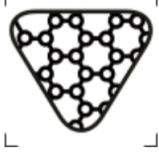
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/fdbfa9256193f2b5f#fdbfa9256193f2b5f>

<p>5.2.11.</p> 	<p>Single <i>sterile</i> barrier system</p>	<p>Indicates a single <i>sterile</i> barrier system</p>	<p>This <i>symbol</i> shall be placed adjacent to or in combination with <i>symbol</i> 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10</p>	<p>NOTE 1 A solid line identifies a <i>sterile</i> barrier system. NOTE 2 Additional information on <i>sterile</i> barrier systems can be found in ISO 11607-1 and ISO 11607-2.</p>
<p>5.2.12.</p> 	<p>Double <i>sterile</i> barrier system</p>	<p>Indicates two <i>sterile</i> barrier systems</p>	<p>This <i>symbol</i> shall be placed adjacent to or in combination with <i>symbol</i> 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10</p>	<p>NOTE 1 A solid line indicates a <i>sterile</i> barrier system. NOTE 2 Additional information on <i>sterile</i> barrier systems can be found in ISO 11607-1 and ISO 11607-2.</p>
<p>5.2.13.</p> 	<p>Single <i>sterile</i> barrier system with protective packaging inside</p>	<p>Indicates a single <i>sterile</i> barrier system with protective packaging inside</p>	<p>This <i>symbol</i> shall be placed adjacent to or in combination with <i>symbol</i> 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10</p>	<p>NOTE 1 The protective packaging located inside the <i>sterile</i> barrier system is designed to prevent damage to the contents or to help with aseptic presentation. It does not provide a microbial barrier to maintain sterility. NOTE 2 Additional information on <i>sterile</i> barrier systems can be found in ISO 11607-1 and ISO 11607-2.</p>
<p>5.2.14.</p> 	<p>Single <i>sterile</i> barrier system with protective packaging outside</p>	<p>Indicates a single <i>sterile</i> barrier system with protective packaging outside</p>	<p>This <i>symbol</i> shall be placed adjacent to or in combination with <i>symbol</i> 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10</p>	<p>NOTE 1 The protective packaging located outside the <i>sterile</i> barrier system is designed to prevent damage to the <i>sterile</i> barrier system and the contents. The protection can be against physical hazards, particulate contamination or other environmental hazards, but it does not include a microbial barrier. NOTE 2 Additional information on <i>sterile</i> barrier systems can be found in ISO 11607-1 and ISO 11607-2.</p>

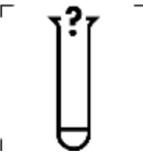
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/fdbfa9256193f2b5f#fdbfa9256193f2b5f>

<p>5.4.6.</p> 	<p>Contains human blood or plasma derivatives</p>	<p>Indicates a <i>medical device</i> that contains or incorporates human blood or plasma derivatives.</p>	<p>The embedded cross may be deleted or replaced with another element appropriate with cultural requirements</p>	
<p>5.4.7.</p> 	<p>Contains a medicinal substance</p>	<p>Indicates a <i>medical device</i> that contains or incorporates a medicinal substance</p>	<p>The embedded cross may be deleted or replaced with another element appropriate with cultural requirements</p>	
<p>5.4.8.</p> 	<p>Contains biological material of animal origin</p>	<p>Indicates a <i>medical device</i> that contains biological tissue, cells, or their derivatives, of animal origin</p>		
<p>5.4.9.</p> 	<p>Contains biological material of human origin</p>	<p>Indicates a <i>medical device</i> that contains biological tissue, cells, or their derivatives, of human origin</p>		
<p>5.4.10.</p> 	<p>Contains hazardous substances</p>	<p>Indicates a <i>medical device</i> that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties</p>		

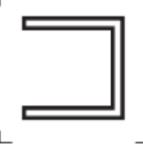
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/00000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/ndbfa9256193f2b5f#ndbfa9256193f2b5f>

5.4.11. 	Contains nano materials	Indicates a <i>medical device</i> that contains nano materials	
5.4.12. 	<i>Single patient multiple use</i>	Indicates a <i>medical device</i> that may be used multiple times (multiple procedures) on a single patient	

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5.5.6.		For IVD performance evaluation only	Indicates an IVD <i>medical device</i> that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.		NOTE 1 A synonym is "IVD for investigational use only". NOTE 2 A <i>medical device</i> that is for IVD performance evaluation only is not intended to be used for an <i>in vitro</i> diagnostic examination for medical purposes (i.e. to yield diagnostic results).	This symbol shall not appear jointly with symbol 5.5.1 which means that the <i>medical device</i> is an <i>in vitro</i> diagnostic <i>medical device</i> intended by the <i>manufacturer</i> to be used for an <i>in vitro</i> diagnostic examination.
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5.6. Transfusion/infusion

5.6.1.		Sampling site	Indicates a <i>medical device</i> or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the <i>medical device</i> or blood container.		NOTE This is not to be associated with a site on a patient where samples are taken.	
5.6.2.		Fluid path	Indicates the presence of a fluid path.			

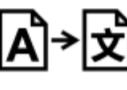
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/00000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/fdbfa9256193f2b5f#fdbfa9256193f2b5f>

5.6.3.		Non-pyrogenic	Indicates a <i>medical device</i> that is non-pyrogenic.		
5.6.4.		Drops per millilitre	Indicates the number of drops per millilitre.	NOTE The number of drops per millilitre is specified; 20 is shown as an example and will be replaced by the appropriate number of drops per millilitre.	
5.6.5.		Liquid filter with pore size	Indicates an infusion or transfusion system of the <i>medical device</i> that contains a filter of a particular nominal pore size.	NOTE The nominal pore size of the filter is specified; 15 is shown as an example and will be replaced by the appropriate pore size.	
5.6.6.		One-way valve	Indicates a <i>medical device</i> with a valve that allows flow in only one direction.	NOTE It is important for the user to know that the flow is only possible in one direction and cannot be reversed.	

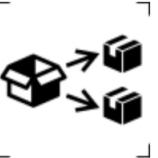
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/ndbfa9256193f2b5f#ndbfa9256193f2b5f>

<p>5.7.1.</p> 	<p>Patient number</p>	<p>Indicates a unique number associated with an individual patient.</p>		<p>NOTE 1 The hash mark (#) is part of the <i>symbol</i>. The patient number appears adjacent to the <i>symbol</i>. NOTE 2 Usage is to indicate a data entry field (e.g. <i>medical device</i> input screen or implant card) or in information provided to the patient.</p>
<p>5.7.2.</p> 	<p>Patient name</p>	<p>Indicates the name of the patient</p>		<p>NOTE Usage is to indicate a data entry field (e.g. <i>medical device</i> input screen or implant card) or in information provided to the patient.</p>
<p>5.7.3.</p> 	<p>Patient identification</p>	<p>Indicates the identification data of the patient</p>		<p>NOTE Usage is to indicate a data entry field (e.g. <i>medical device</i> input screen or implant card) or in information provided to the patient</p>
<p>5.7.4.</p> 	<p>Patient information website</p>	<p>Indicates a website where a patient can obtain additional information on the medical product</p>	<p>This <i>symbol</i> shall be accompanied by the web address adjacent to the <i>symbol</i></p>	<p>NOTE Usage is to indicate location of information available to the patient</p>

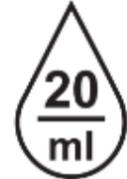
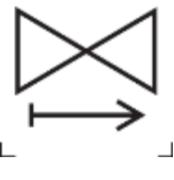
<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/fdbfa9256193f2b5f#fdbfa9256193f2b5f>

5.7.5.		Health care centre or doctor	To indicate the address of the health care centre or doctor where medical information about the patient may be found	This <i>symbol</i> shall be accompanied, adjacent to the <i>symbol</i> , by the address of the health care centre or doctor	<p>NOTE 1 The embedded cross can be deleted or replaced with another element appropriate with cultural requirements.</p> <p>NOTE 2 Usage is to indicate a data entry field (e.g. <i>medical device</i> input screen or implant card) or in information provided to the patient</p>	
5.7.6.		Date	To identify the date that information was entered or a medical procedure took place	This <i>symbol</i> shall be accompanied, adjacent to the <i>symbol</i> , by the date appropriate for the use of the <i>symbol</i>	<p>NOTE Usage is to indicate a data entry field (e.g. <i>medical device</i> input screen or implant card) or in information provided to the patient</p>	
5.7.7.		<i>Medical device</i>	Indicates the item is a <i>medical device</i>			
5.7.8.		Translation	To identify that the original <i>medical device</i> information has undergone a translation which supplements or replaces the original information	This <i>symbol</i> shall be accompanied by the name and address of the entity that is responsible for the translation activity, adjacent to the <i>symbol</i> .	<p>NOTE If multiple <i>symbol</i>s (i.e., <i>Authorized Representative</i>, <i>Importer</i>, <i>Distributor</i>, <i>Translation</i>, or <i>Repackaging</i>) identify the same responsible entity, the name and address need not be duplicated.</p>	<p>This <i>symbol</i> shall only be used when the translation activity was undertaken by someone other than the <i>manufacturer</i>.</p>

<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/fdbfa9256193f2b5f#fdbfa9256193f2b5f>

<p>5.7.9.</p> 	<p>Repackaging</p>	<p>To identify that a modification to the original <i>medical device</i> packaging configuration has occurred</p>	<p>This <i>symbol</i> shall be accompanied by the name and address of the entity that is responsible for the repackaging activity, adjacent to the <i>symbol</i></p>	<p>NOTE 1 Depending on the authority having jurisdiction, additional information (i.e. date of repackaging) can be needed.</p> <p>NOTE 2 If multiple <i>symbol</i>s (i.e., Authorized Representative, <i>Importer</i>, <i>Distributor</i>, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.</p>	<p>This <i>symbol</i> shall only be used when the repackaging activity was undertaken by someone other than the <i>manufacturer</i>.</p>
<p>5.7.10.</p> 	<p>Unique Device Identifier</p>	<p>Indicates a carrier that contains Unique Device Identifier information</p>	<p>The use of this <i>symbol</i> is optional, but may be used when multiple data carriers are present on the label. If used, this <i>symbol</i> shall be placed adjacent to the Unique Device Identifier carrier.</p>	<p>NOTE Used to identify which information is associated with Unique Device Identifier</p>	

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5.6.4.		Drops per millilitre	Indicates the number of drops per millilitre.	NOTE The number of drops per millilitre is specified; 20 is shown as an example and will be replaced by the appropriate number of drops per millilitre.
5.6.5.		Liquid filter with pore size	Indicates an infusion or transfusion system of the <i>medical device</i> that contains a filter of a particular nominal pore size.	NOTE The nominal pore size of the filter is specified; 15 is shown as an example and will be replaced by the appropriate pore size.
5.6.6.		One-way valve	Indicates a <i>medical device</i> with a valve that allows flow in only one direction.	NOTE It is important for the user to know that the flow is only possible in one direction and cannot be reversed.

<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/00000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/ndbfa9256193f2b5f#ndbfa9256193f2b5f>

A.9 Examples of use of symbol 5.1.8, “ Importer ”

[Add/View comments \(0\)](#)



Name
Address

A.10 Examples of use of symbol 5.1.9, “ Distributor ”

[Add/View comments \(0\)](#)



Name
Address

A.11 Examples of use of symbol 5.1.11, “Country of manufacture”

[Add/View comments \(0\)](#)

NOTE CC is the two or three letter country code as defined in ISO 3166-1.



2019-06



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A.19 Examples of use of symbol 5.7.8, "Translation"

[Add/View comments \(0\)](#)



Name
Address

A.20 Examples of use of symbol 5.7.9, "Repackaging"

[Add/View comments \(0\)](#)



Name
Address

A.19 Examples of use of symbol 5.7.8, "Translation"

[Add/View comments \(0\)](#)



Name
Address

A.20 Examples of use of symbol 5.7.9, "Repackaging"

[Add/View comments \(0\)](#)



Name
Address

<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/000000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/ndbfa9256193f2b5f#ndbfa9256193f2b5f>

A.21 Examples of use of symbol 5.7.10, "Unique Device Identifier"

[Add/View comments \(0\)](#)



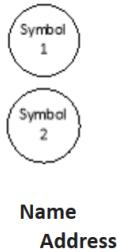
(01)01234567891011(17)200526(10)123456789

A.22 Explanation on how to deal with multiple symbols used together

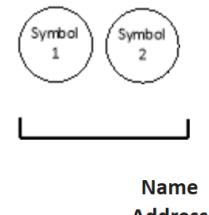
The symbols EC REP, Importer, Distributor, Repackaging and Translation each have a note indicating that when multiple symbols all apply to the same responsible entity, the name and address need not be duplicated. The following shows some of the possible ways that may be accomplished.

The intent is for the name and address to be unambiguously associated with the symbols. Additional graphical elements may be used for the association. Several additional graphical elements are shown below.

When two symbols apply, the symbols may appear grouped vertically or horizontally with the name and address adjacent to the symbols [i.e. either above, below, to the left, or to the right].

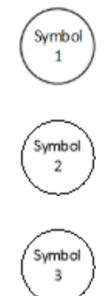
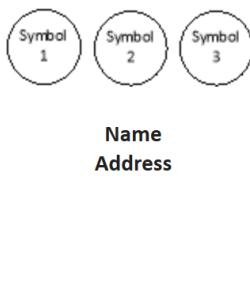


Name
Address

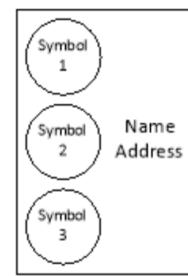


Name
Address

When three symbols apply, the symbols may appear grouped vertically or horizontally with the name and address adjacent to the symbols [i.e. either above, below, to the left, or to the right].



Name
Address



Name
Address

<https://standardsdevelopment.bsigroup.com/drafts/2018-03581/00000000030387822?standardsReference=BS%20EN%20ISO%2015223-1#/nfbfa9256193f2b5f#nfbfa9256193f2b5f>

When four or five *symbols* apply, the symbols may appear grouped in any convenient way that is unambiguous, with the name and address adjacent to the *symbols* . [i.e. either above, below, to the left, to the right, or with the grouping].

