



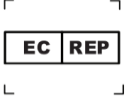



























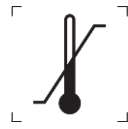
Label Template:

S.N O.	Requirement ID#	Element	Content/Symbol
1	23.2(a)	Name Or Trade Name	Brand Name
2	23.2(b)	Identify the device	Option: 1 REF Option: 2 Description of the device. Option:3 QTY
3	23.2(c)	registered trademark of the manufacturer and the address	 <p>Name and address should be written next to the symbol.</p> <p>Example:</p>  
4	23.2 (d)	authorised representative and address (If applicable)	 <p>Name and address should be written next to the symbol.</p> <p>Example:</p>  

5	23.2 (e)	medicinal substance, including a human blood or plasma derivative	
		Tissues or cells of human origin	
		Tissues or cells of animal origin	
6	23.2(f)	CMR Substances	
7	23.2 (g)	LOT NUMBER or SERIAL NUMBER	<p>  OR </p> <p>Example:</p> <p> ABC123  ABC123</p>

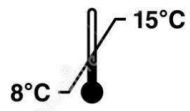
8	23.2 (h)	UDI Carrier	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">UDI</div>  <div style="font-size: 8px;"> (01)01234567891011 (11)200622 (17)240622 (21)88888888 </div> </div> <hr/> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">UDI</div>  <div style="font-size: 8px;"> (01)01234567891011(11)200622(17)240622(21)88888888 </div> </div>
9	23.2 (i)	Time limit for using or implanting the device * YYYY-Year MM-Month DD-Date	<div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"></div> <div>YYYY-MM-DD</div> </div> <p style="text-align: center;">OR</p> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"></div> <div>YYYY-MM</div> </div> <p>Example:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"></div> <div>2016-12-01</div> <div style="border: 1px solid black; padding: 2px; margin-left: 10px;"></div> </div> <div style="text-align: right; margin-top: 5px;">2016-06</div>
10	23.2 (j)	Date of manufacture * YYYY-Year MM-Month DD-Date	<div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"></div> <div>YYYY-MM-DD</div> </div> <p style="text-align: center;">OR</p> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;"></div> <div>YYYY-MM</div> </div>

			<p>Example:</p> 
11	23.2 (k)	Special storage/handling conditions	 <p>Fragile, handle with care</p>
			 <p>Keep away from sunlight</p>
			 <p>Protect from heat and radio-active sources</p>
			 <p>Keep Dry</p>
			 <p>Lower limit of temperature</p>
			 <p>Upper limit of temperature</p>



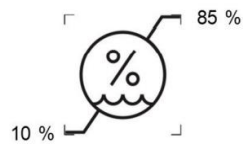
Temperature limit

Example:



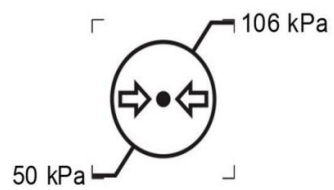
Humidity limitation







Example:








Atmospheric pressure limitation

Example:



12	23.2(I)	Device is supplied sterile	 Sterile
			 Sterile using aseptic processing techniques
			 Sterilized using ethylene oxide
			 Sterilized using irradiation
			 Sterilized using steam or dry heat
			 Do not resterilize

			 <p>Non-sterile</p>
			 <p>Sterile fluid path</p> <p>Example:</p> <p>Medical device contains a sterile fluid path that has been sterilized using ethylene oxide</p> 
13	23.2 (m)	Warnings or precautions	 <p>Caution</p>
14	23.2 (n)	device is intended for single use	 <p>Do not re-use</p>
15	23.2 (o)	a single-use device that has been reprocessed	Reprocessing cycles
16	23.2 (p)	device is custom-made	'custom-made'

17	23.2 (q)	device is a medical device	<div style="display: flex; align-items: center; justify-content: center;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 10px;">MD</div> Medical Device </div>
18	23.2(r)	composed of substances or of combinations of substances	qualitative composition and quantitative information
19	23.2 (s)	for active implantable devices, the serial number, and for other implantable devices, the serial number, or the lot number.	<p>for active implantable devices, the serial number</p> <div style="display: flex; align-items: center; justify-content: center; margin-bottom: 10px;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 10px;">SN</div> </div> <p>other implantable devices, the serial number or the lot number.</p> <div style="display: flex; align-items: center; justify-content: center; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 20px;">SN</div> OR <div style="border: 1px solid black; padding: 2px 5px; margin-left: 20px;">LOT</div> </div>