



# *SERVICE BULLETIN*

PN: 21174579

**RELEASE DATE:** July 3, 2017

**REVISION DATE(S):** September 29, 2017 (Rev B), March 15, 2019 (Rev C)

**MODEL:** All LOX Portables and Reservoirs

**ISSUE:** LOX label service kits

**NOTES:** CAIRE has created new symbolic labels for all LOX reservoirs and portable units. Prior to this change, CAIRE maintained a large variety of LOX labels in stock due to the number of different languages throughout our markets. The use of symbolic labels on LOX reservoirs and portables will greatly reduce the number of labels that are currently required. In Europe, when replacing labelling on any CAIRE medical device, it is a regulatory requirement that the number of the notified body who authorized the medical device at the time of manufacture not be modified. In order to assist our European customers, CAIRE Inc. has created service kits for each unit type. The service kits are specific to the appropriate CE markings that are required for each unit. The CE requirements are based on the model and the age of the device. The European kits will include a symbolic warning label, a reference guide for the symbols, and a replacement CE label. U.S. customers are not required to maintain CE labeling on LOX reservoirs and portables. Because of this, CAIRE has created separate U.S. label service kits that only include the symbolic warning label and a reference guide for the symbols.

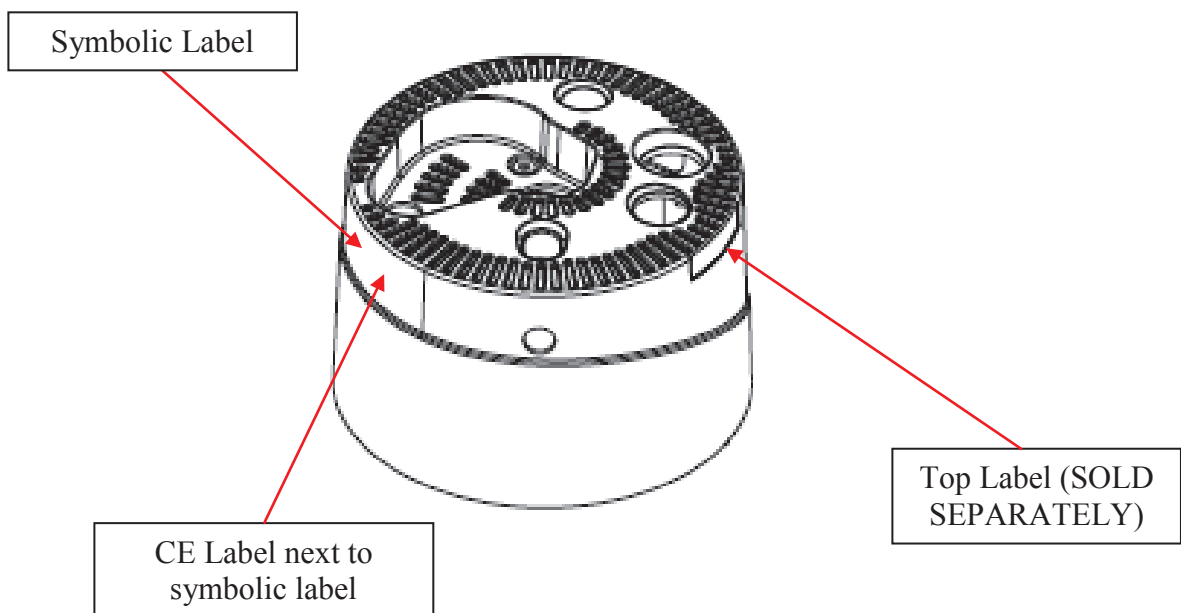
The tables below detail the applicable service kits for reservoirs and portable units. European customers can determine the age of manufacture by referencing each unit's serial number. Diagrams are also provided below that show the location where each label in the kit should be applied.

**Non-CE Mark Kits (for the U.S.A and any country which does not require CE marked products)**

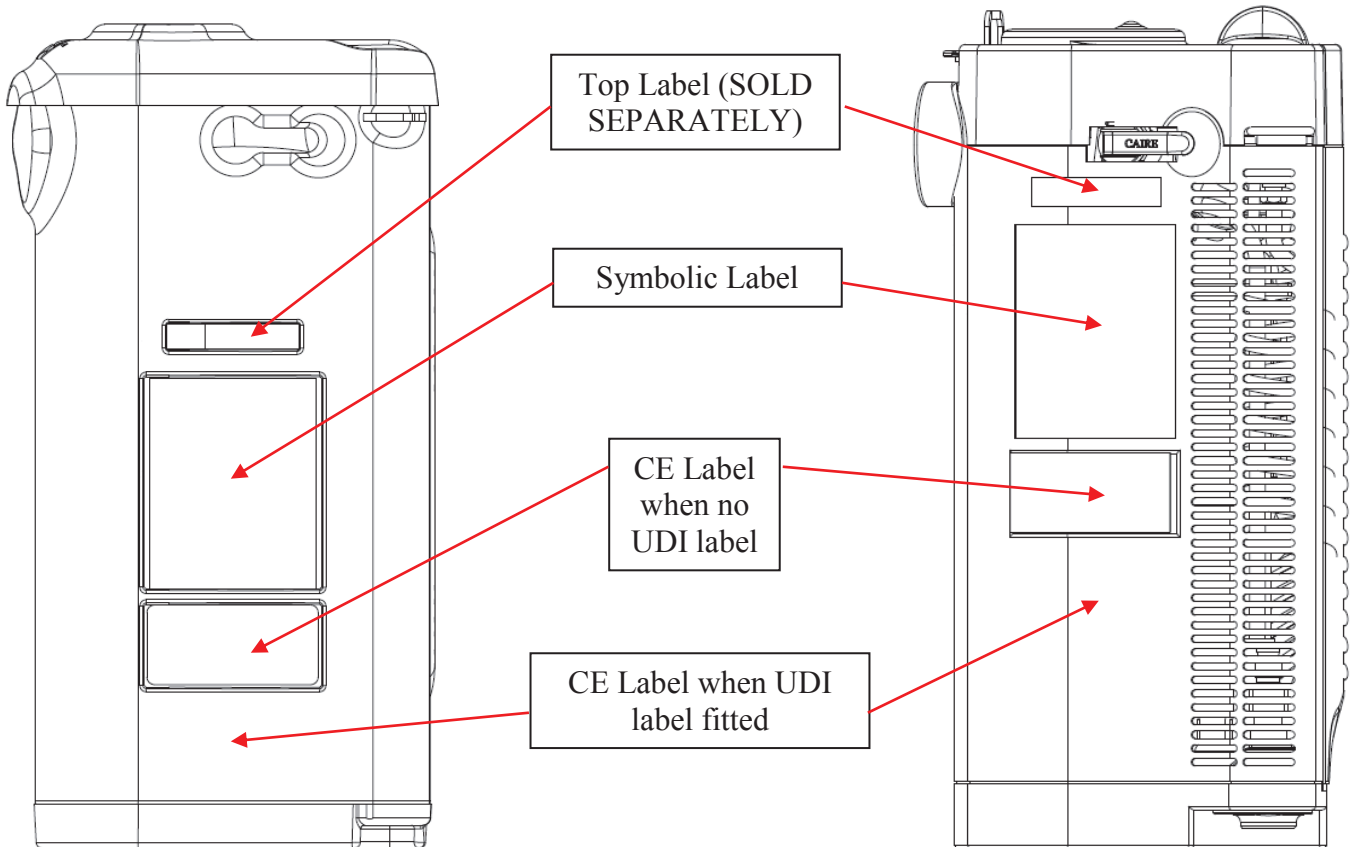
<b>Model</b>	<b>Label Service Kit Part Number</b>
Liberator	21194752
Stroller, Sprint, Spirit	21194754
H300 / Plus	21194757
HELiOS Universal Reservoirs	21194758
H850 / Marathon	21194759
C1000/C1000T	21194760
Companion Reservoirs	21194761

**European Kits:**

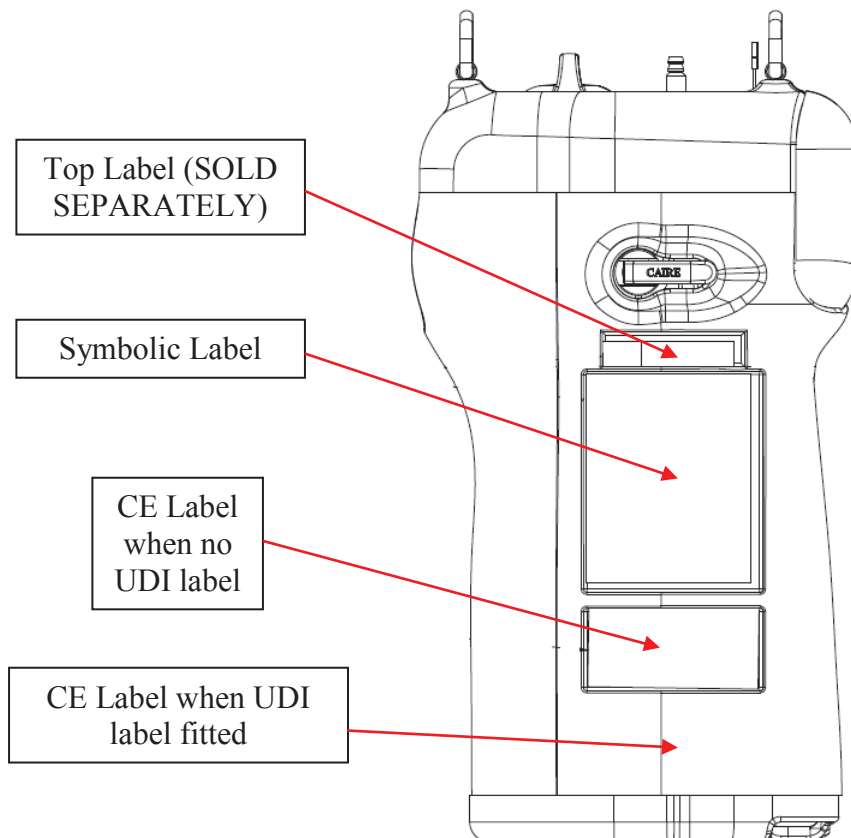
Liberator	Date Range	SN format	Range
<b>CE0029</b>  <b>Label Kit Ref: 21152753</b>	Prior 2006	For Liberators manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
	2006 - May 7, 2016	<p style="text-align: center;"><b>CB B30 10 29 0964</b></p> <p style="text-align: center;">             Designates Manufacturing Location    Designates Reservoir Product Code    Designates Year    Designates Week of the Year    Designates Number of Specific Unit Produced that Week           </p>	<b>CBB3006XXXXXX-</b> <b>CBB301618XXXX</b>  X=any value
<b>CE0459</b>  <b>Label Kit Ref: 21150538</b>	May 9, 2016 - Present	<p style="text-align: center;"><b>CB B30 10 29 0964</b></p> <p style="text-align: center;">             Designates Manufacturing Location    Designates Reservoir Product Code    Designates Year    Designates Week of the Year    Designates Number of Specific Unit Produced that Week           </p>	<b>CBB301619XXXX-</b> <b>Present</b>  X=any value



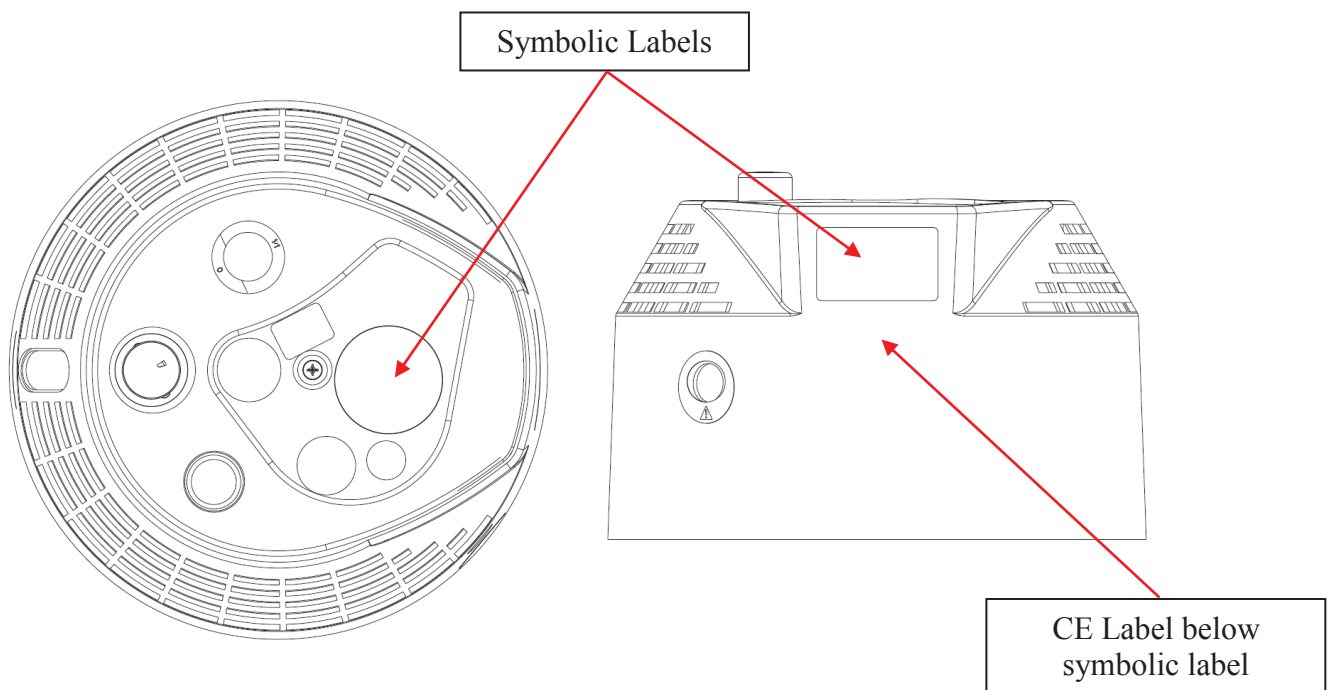
Stroller / Sprint / Hi-Flow	Date Range	SN format	Range
<b>CE0029</b>  <b>Label Kit Ref: 21152754</b>	Prior 2006	For Strollers and Sprints manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
	2006 - May 7, 2016	<div style="text-align: center;"> <b>CB B31 10 29 0964</b> </div> <div style="display: flex; justify-content: space-around; text-align: center; font-size: small;"> <div>Designates Manufacturing Location</div> <div>Designates Reservoir Product Code</div> <div>Designates Year</div> <div>Designates Week of the Year</div> <div>Designates Number of Specific Unit Produced that Week</div> </div>	<b>CBB3106XXXXXX-CBB311618XXXX</b>  X=any value
<b>CE0459</b>  <b>Label Kit Ref: 21150537</b>	May 9, 2016 - Present	<div style="text-align: center;"> <b>CB B31 10 29 0964</b> </div> <div style="display: flex; justify-content: space-around; text-align: center; font-size: small;"> <div>Designates Manufacturing Location</div> <div>Designates Reservoir Product Code</div> <div>Designates Year</div> <div>Designates Week of the Year</div> <div>Designates Number of Specific Unit Produced that Week</div> </div>	<b>CBB311619XXXX-Present</b>  X=any value



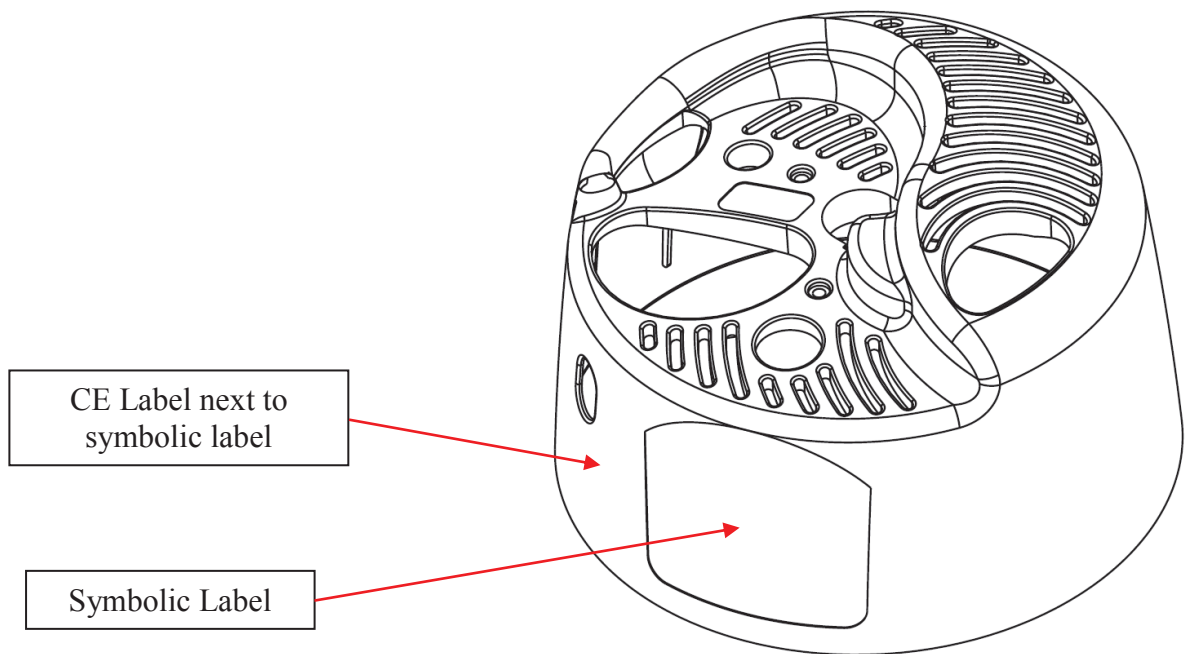
Spirit	Date Range	SN format	Range
CE0029 Label Kit Ref: 21152754	Prior 2006	For Spirits manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
	2006 - May 7, 2016	<p style="text-align: center;"><b>CB B37 10 29 0964</b></p> <p style="text-align: center;">             Designates Designates Designates Designates Designates              Manufacturing Reservoir Year Week of Number              Location Product Code of the Year of Specific              Unit Produced              that Week           </p>	<b>CBB3706XXXXXX-</b> <b>CBB371618XXXX</b>  X=any value
CE0459 Label Kit Ref: 21150537	May 9, 2016 - Present	<p style="text-align: center;"><b>CB B37 10 29 0964</b></p> <p style="text-align: center;">             Designates Designates Designates Designates Designates              Manufacturing Reservoir Year Week of Number              Location Product Code of the Year of Specific              Unit Produced              that Week           </p>	<b>CBB371619XXXX-</b> Present  X=any value



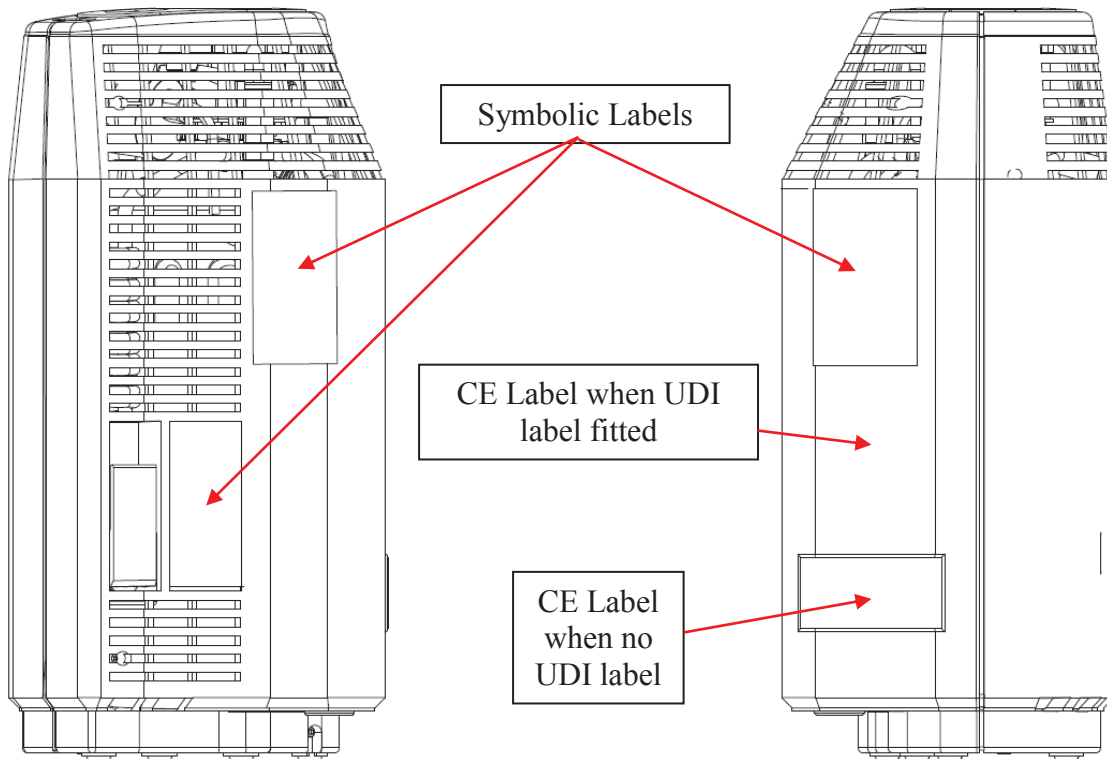
Companion Reservoirs	Date Range	SN format	Range
<b>CE0050</b> <b>Label Kit Ref:</b> <b>21150541</b>	Prior March 2010	For Companion Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
<b>CE0029</b> <b>Label Kit Ref:</b> <b>21152758</b>	March 2010 - May 7, 2016	<p style="text-align: center;"><b>CB B30 10 29 0964</b></p> <p style="text-align: center;">           Designates Manufacturing Location    Designates Reservoir Product Code    Designates Year    Designates Week of the Year    Designates Number of Specific Unit Produced that Week         </p>	<b>CBB3010XXXXXX-</b> <b>CBB301618XXXX</b>  X=any value
<b>CE0459</b> <b>Label Kit Ref:</b> <b>21152849</b>	May 9, 2016 - Present	<p style="text-align: center;"><b>CB B30 10 29 0964</b></p> <p style="text-align: center;">           Designates Manufacturing Location    Designates Reservoir Product Code    Designates Year    Designates Week of the Year    Designates Number of Specific Unit Produced that Week         </p>	<b>CBB301619XXXX-</b> Present  X=any value



Helios Universal Reservoirs (U36/U46)	Date Range	SN format	Range
<b>CE0050</b>  <b>Label Kit Ref: 21153004</b>	Prior March 2010	For Helios Universal Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
<b>CE0029</b>  <b>Label Kit Ref: 21153006</b>	March 2010 - May 7, 2016	<p style="text-align: center;"><u>CB</u> <u>B30</u> <u>10</u> <u>29</u> <u>0964</u></p> <p style="text-align: center;"> <span style="margin-right: 40px;">Designates Manufacturing Location</span> <span style="margin-right: 40px;">Designates Reservoir Product Code</span> <span style="margin-right: 40px;">Designates Year</span> <span style="margin-right: 40px;">Designates Week of the Year</span> <span>Designates Number of Specific Unit Produced that Week</span> </p>	<b>CBB3010XXXXXX-</b> <b>CBB301618XXXX</b>  X=any value
<b>CE0459</b>  <b>Label Kit Ref: 21153005</b>	May 9, 2016 - Present	<p style="text-align: center;"><u>CB</u> <u>B30</u> <u>10</u> <u>29</u> <u>0964</u></p> <p style="text-align: center;"> <span style="margin-right: 40px;">Designates Manufacturing Location</span> <span style="margin-right: 40px;">Designates Reservoir Product Code</span> <span style="margin-right: 40px;">Designates Year</span> <span style="margin-right: 40px;">Designates Week of the Year</span> <span>Designates Number of Specific Unit Produced that Week</span> </p>	<b>CBB301619XXXX-</b> <b>Present</b>  X=any value



Companion Portable (C1000/C1000T)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150701	Prior March 2010	For Companion Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21131485	March 2010 - May 7, 2016	<p style="text-align: center;"><b>CB B31 10 29 0964</b></p> <p style="text-align: center;">             Designates Designates Designates Designates Designates              Manufacturing Reservoir Year Week of Number              Location Product Code of the Year of Specific              Unit Produced that Week           </p>	<b>CBB3110XXXXXX- CBB311618XXXX</b>  X=any value
CE0459 Label Kit Ref: 21152747	May 9, 2016 - Present	<p style="text-align: center;"><b>CB B31 10 29 0964</b></p> <p style="text-align: center;">             Designates Designates Designates Designates Designates              Manufacturing Reservoir Year Week of Number              Location Product Code of the Year of Specific              Unit Produced that Week           </p>	<b>CBB311619XXXX- Present</b>  X=any value

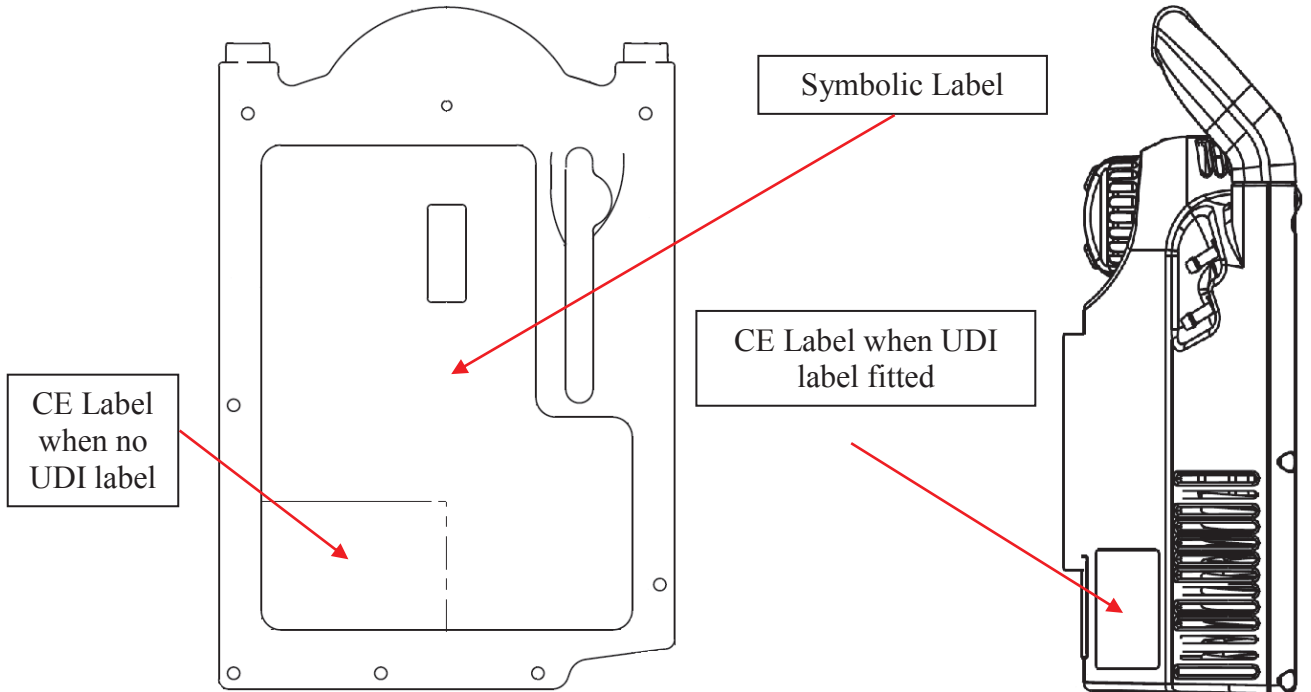




Helios H300/Plus Portable	Date Range	SN format	Range
<b>CE0050</b> Label Kit Ref: 21150540	Prior March 2010	For Helios H300/Plus Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
<b>CE0029</b> Label Kit Ref: 21152761	March 2010 - May 7, 2016		<b>CBB3110XXXXXX-</b> <b>CBB311618XXXX</b>  X=any value
<b>CE0459</b> Label Kit Ref: 21152760	May 9, 2016 - Present		<b>CBB311619XXXX-</b> Present  X=any value

Helios H850/Marathon Portable	Date Range	SN format	Range
<b>CE0050</b> Label Kit Ref: 21153040	Prior March 2010	For Helios H850/Marathon Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
<b>CE0029</b> Label Kit Ref: 21153041	March 2010 - May 7, 2016		<b>CBB3110XXXXXX-</b> <b>CBB311618XXXX</b>  X=any value

<b>CE0459</b> <b>Label Kit Ref:</b> <b>21153042</b>	May 9, 2016 - Present	<b>CB B31 10 29 0964</b>	<b>CBB311619XXXX-</b> Present  X=any value	
		Designates Manufacturing Location		Designates Reservoir Product Code



Should you have any issues with identifying the correct notified body number for your device, please contact Customer or Technical Service with the serial number of the device.

**CONTACT:** For technical questions or concerns, contact Technical Service:  
USA: 800-482-2473  
[www.cairemedical.com](http://www.cairemedical.com)  
Europe: +44 1344 403100  
[www.cairemedical.com](http://www.cairemedical.com)

For ordering information or general inquires, contact Customer Service:  
USA: 800-482-2473  
[www.cairemedical.com](http://www.cairemedical.com)  
Europe: +44 1344 403100  
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