



SERVICE BULLETIN

PN: 21174579

RELEASE DATE: July 3, 2017

REVISION DATE(S): September 29, 2017 (Rev B), March 15, 2019 (Rev C), March 01, 2020 (Rev D),
December 05, 2022 (Rev E).

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.

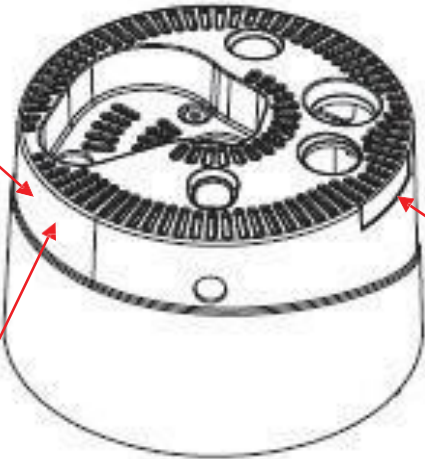
Non-CE Mark Kits (for the U.S.A and any country which does not require CE marked products)

Model	Label Service Kit Part Number
Liberator	21194752
Stroller, Sprint, Spirit	21194754
H300 / Plus	21194757
HELiOS Standard Reservoirs	21194755
HELiOS Universal Reservoirs	21194758
H850 / Marathon	21194759
C1000/C1000T	21194760
Companion Reservoirs	21194761

European Kits:

Liberator	Date Range	SN format	Range
CE0029 Label Kit Ref: 21152753	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;">CB B30 10 29 0964</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>	CBB3006XXXXXX- CBB301618XXXX X=any value
CE0459 Label Kit Ref: 21150538	May 9, 2016 - Present	<p style="text-align: center;">CB B30 10 29 0964</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>	CBB301619XXXX- Present X=any value

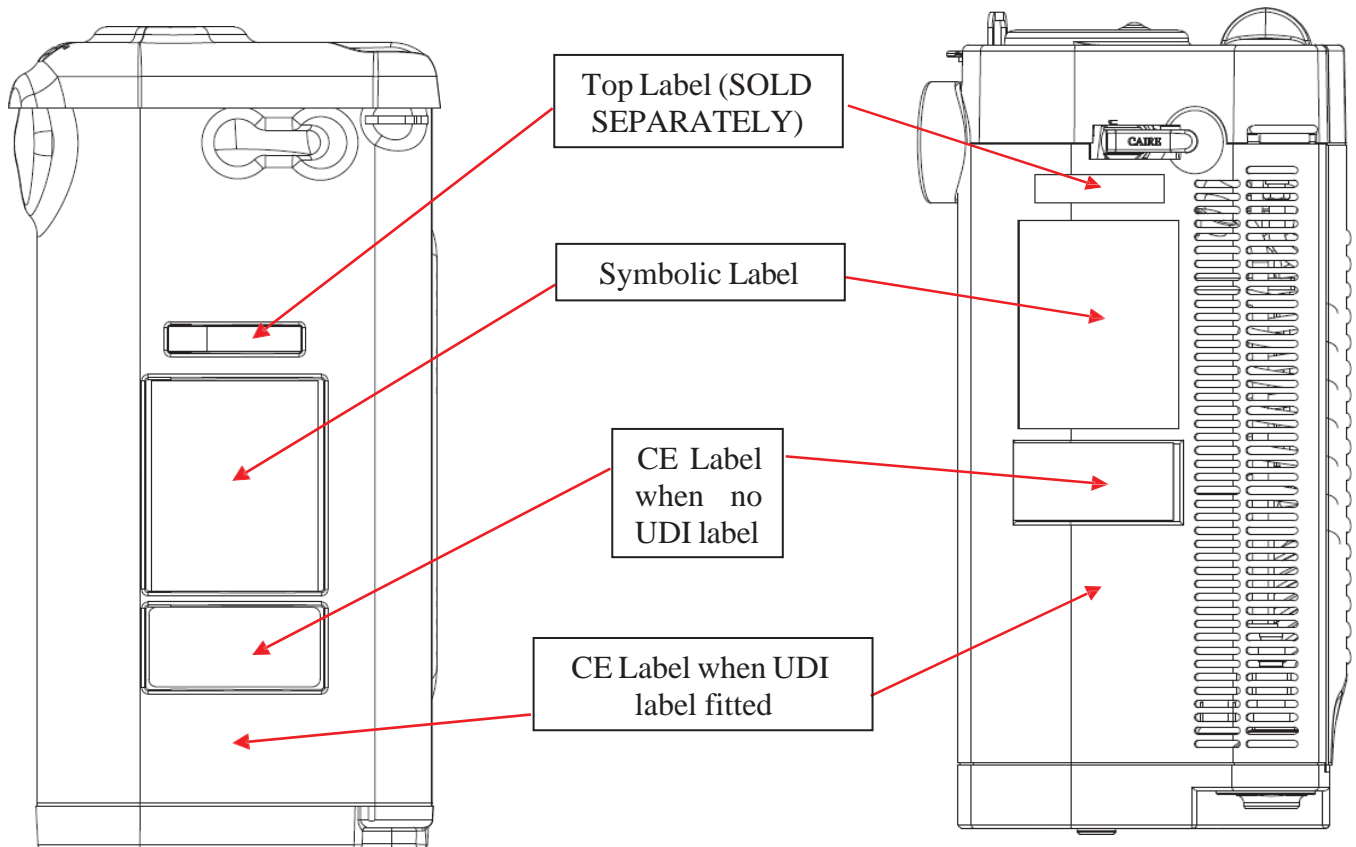
Symbolic Label



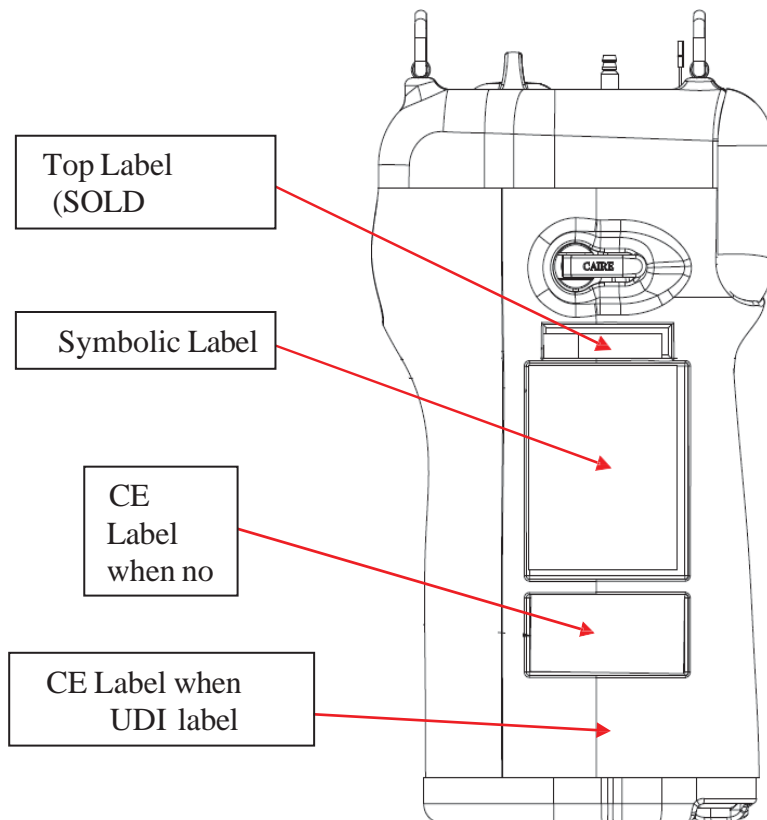
CE Label next to symbolic label

Top Label (SOLD SEPARATELY)

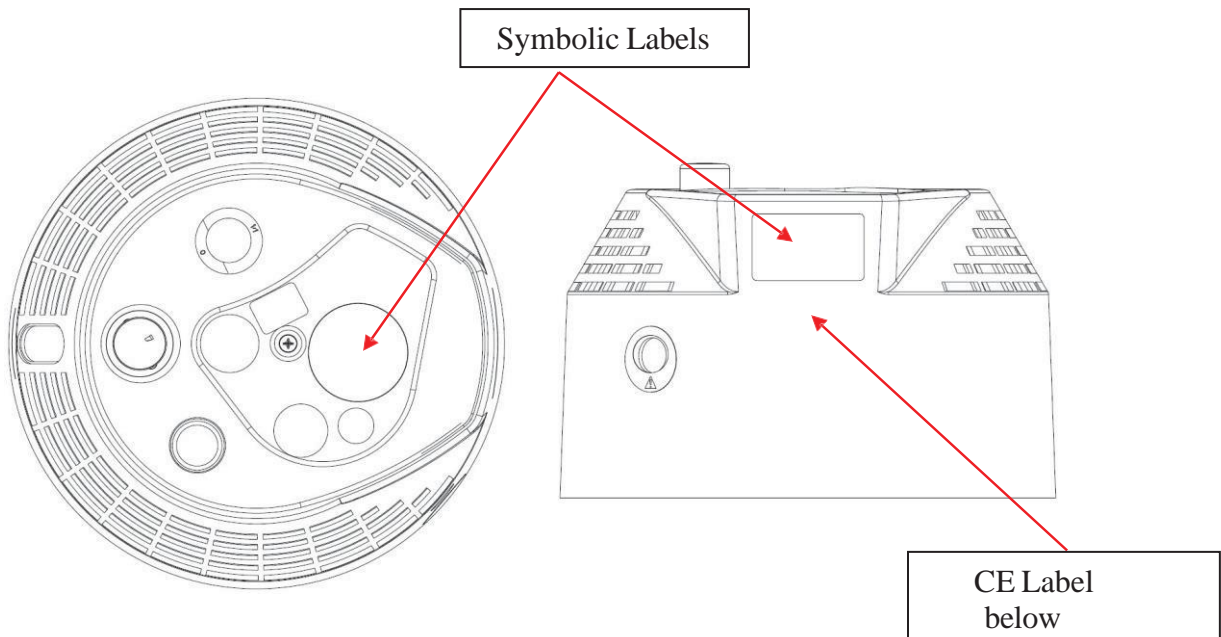
Stroller / Sprint / Hi-Flow	Date Range	SN format	Range
CE0029 Label Kit Ref: 21152754	Prior 2006	For Strollers and Sprints manufactured before 2006, the serial number was nine or ten numerical digits.	All numerical only serial numbers.
	2006 - May 7, 2016	<p style="text-align: center;">CB B31 10 29 0964</p> <p style="text-align: center;"> Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product Code the Year of Specific Unit Produced that Week </p>	CBB3106XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21150537	May 9, 2016 - Present	<p style="text-align: center;">CB B31 10 29 0964</p> <p style="text-align: center;"> Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product Code the Year of Specific Unit Produced that Week </p>	CBB311619XXXX- Present 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;">CB B37 10 29 0964</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>	CBB3706XXXXXX- CBB371618XXXX X=any value
CE0459 Label Kit Ref: 21150537	May 9, 2016 - Present	<p style="text-align: center;">CB B37 10 29 0964</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>	CBB371619XXXX- Present X=any value



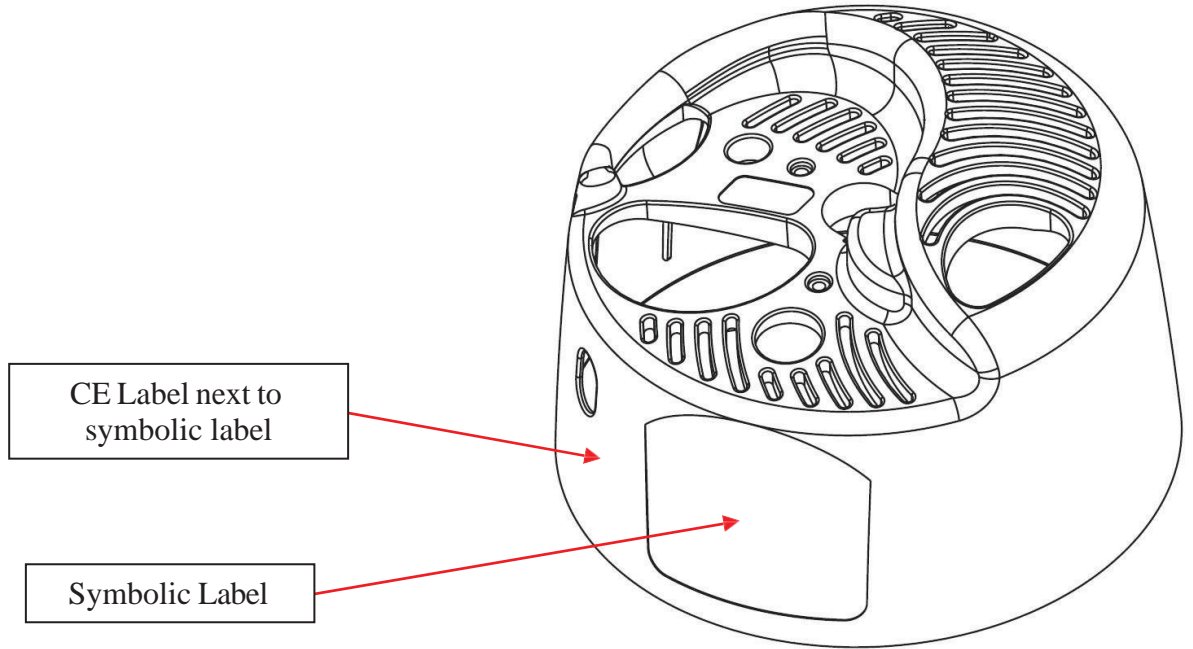
Companion Reservoirs	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150541	Prior March 2010	For Companion Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152758	March 2010 - May 7, 2016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



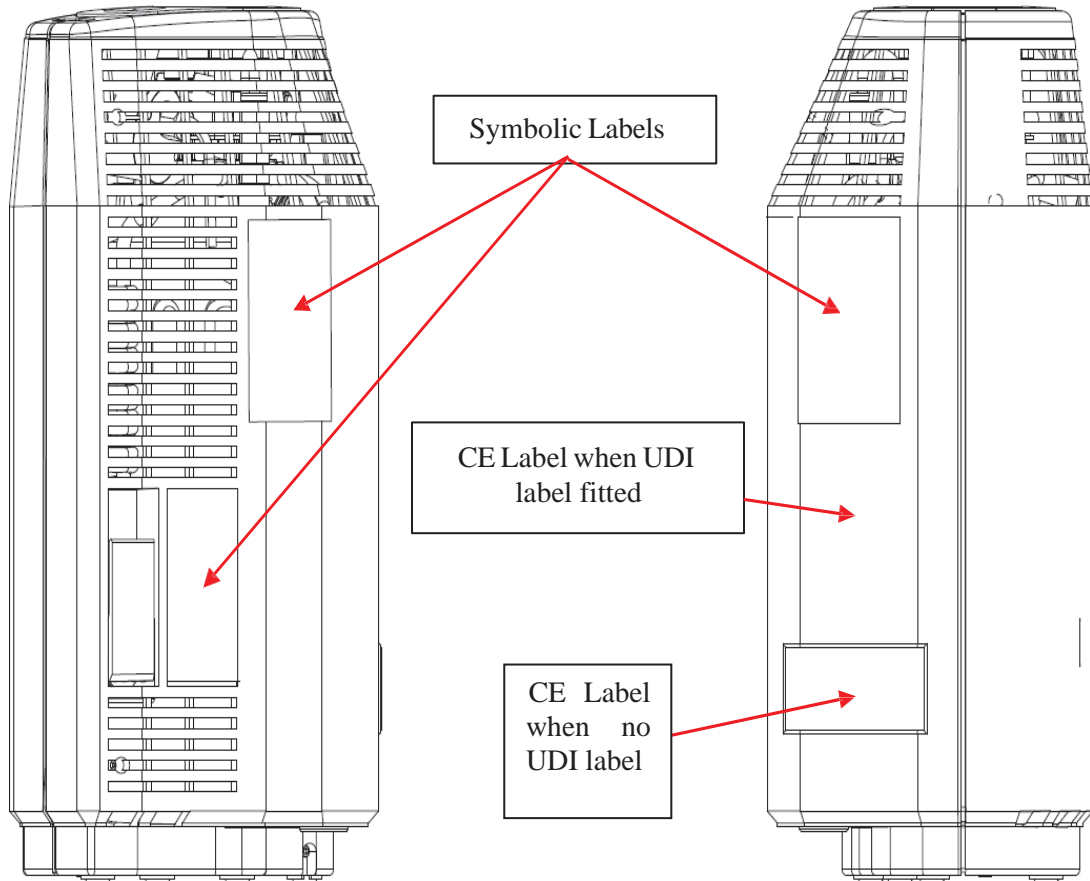
Helios Standard Reservoirs (H36/H46)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150539	Prior March 2010	For Helios Standard Reservoir units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21152759	March 2010 - May 7, 2016	<p style="text-align: center;">CB B30 10 29 0964</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>	CBB3007XXXXXX-CBB301618XXXX X=any value
CE0459 Label Kit Ref: 21152755	May 9, 2016 - Present	<p style="text-align: center;">CB B30 10 29 0964</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>	CBB301619XXXX-Present X=any value

Helios Universal Reservoirs (U36/U46)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21153004	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.
CE0029 Label Kit Ref: 21153006	March 2010 - May 7, 2016	<p style="text-align: center;">CB B30 10 29 0964</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>	CBB3010XXXXXX-CBB301618XXXX X=any value

<p>CE0459 Label Kit Ref: 2115300 5</p>	<p>May 9, 2016 - Present</p>	<p style="text-align: center;">CB B30 10 29 0964</p> <p style="text-align: center;"> Designates Designates Designates Designates Designates Manufacturing Reservoir Year Week of Number Location Product Code the Year of Specific Unit Produced that Week </p>	<p>CBB301619XXXX- Present</p> <p>X=any value</p>
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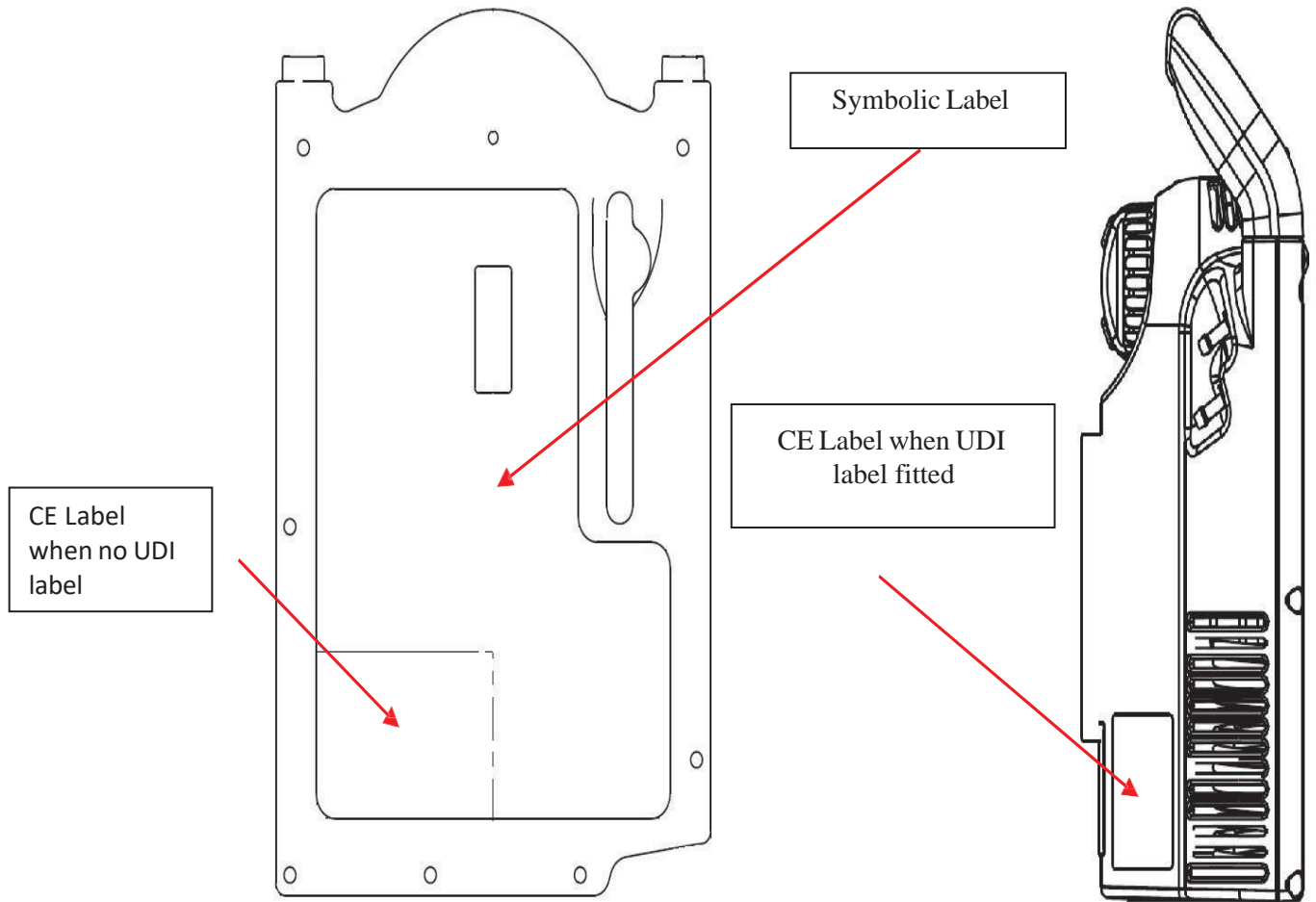
Companion Portable (C1000/C1000T)	Date Range	SN format	Range
CE0050 Label Kit Ref: 21150701	Prior March 2010	For Companion Portable units manufactured before March 2010, the serial number was five or eight numerical digits.	All numerical only serial numbers.
CE0029 Label Kit Ref: 21131485	March 2010 - May 7, 2016	<p style="text-align: center;">CB B31 10 29 0964</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>	CBB3110XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21152747	May 9, 2016 - Present	<p style="text-align: center;">CB B31 10 29 0964</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>	CBB311619XXXX- Present X=any value



Helios H300/Plus Portable	Date Range	SN format	Range
CE0050 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.
CE0029 Label Kit Ref: 21152761	March 2010 - May 7, 2016		CBB3110XXXXXX- CBB311618XXXX X=any value
CE0459 Label Kit Ref: 21152760	May 9, 2016 - Present		CBB311619XXXX- Present X=any value

Helios H850/Marathon Portable	Date Range	SN format	Range
CE0050 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.
CE0029 Label Kit Ref: 21153041	March 2010 - May 7, 2016		CBB3110XXXXXX- CBB311618XXXX X=any value

CE0459 Label Kit Ref: 21153042	May 9, 2016 - Present	CB B31 10 29 0964	CBB311619XXXX- 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

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Europe: +44 (0) 118 936 7060

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For ordering information or general inquiries, contact Customer Service:

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