


Laerdal

helping save lives

00014236 Rev N

EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway																						
Manufacturing site:	Dong Guan Eastek Plastics & Electronics Co., Limited Jinxiaotang Industrial Estate, Zhutang District, Fenggang Town, Dongguang City, Guangdong Province, 523682 P.R.China																						
Product Name:	Laerdal Compact Suction Unit 4 (LCSU 4)																						
Product Options:	<table> <tr> <td>880051</td> <td>LCSU 4 800 ml Complete unit</td> </tr> <tr> <td>880061</td> <td>LCSU 4 300 ml Complete unit</td> </tr> <tr> <td>880052</td> <td>LCSU 4 800 ml RTCA, Complete unit</td> </tr> <tr> <td>880062</td> <td>LCSU 4 300 ml RTCA, Complete unit</td> </tr> <tr> <td>88005127</td> <td>LCSU 4, 800 ml (KOR)</td> </tr> <tr> <td>88006127</td> <td>LCSU 4, 300 ml (KOR)</td> </tr> <tr> <td>88005227</td> <td>LCSU 4, 800 ml, RTCA(KOR)</td> </tr> <tr> <td>88006227</td> <td>LCSU 4, 300 ml, RTCA(KOR)</td> </tr> <tr> <td>88007105</td> <td>LCSU 4, 800 ml (J)</td> </tr> <tr> <td>881151</td> <td>LCSU 4, Replacement unit</td> </tr> <tr> <td>881152</td> <td>LCSU 4, RTCA, Replacement unit</td> </tr> </table>	880051	LCSU 4 800 ml Complete unit	880061	LCSU 4 300 ml Complete unit	880052	LCSU 4 800 ml RTCA, Complete unit	880062	LCSU 4 300 ml RTCA, Complete unit	88005127	LCSU 4, 800 ml (KOR)	88006127	LCSU 4, 300 ml (KOR)	88005227	LCSU 4, 800 ml, RTCA(KOR)	88006227	LCSU 4, 300 ml, RTCA(KOR)	88007105	LCSU 4, 800 ml (J)	881151	LCSU 4, Replacement unit	881152	LCSU 4, RTCA, Replacement unit
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to which this declaration relates is in conformity with

Essential Requirements of the Council Directive 93/42/EEC for Medical Devices, as amended; and Council Directive 2011/65/EU on Restriction on the use of certain hazardous substance (RoHS)

All supporting documentation is retained by the manufacturer.

Classification: The LCSU 4 is class IIa according to rule 11 of Annex IX of the EU Medical Device Directive.

Laerdal Medical AS is certified by DNV GL Presafe AS to ISO13485:2016.

Conformity Assessment of LCSU 4 is based on the principles described in Annex II of the Directive 93/42/EEC, minus Section 4

DocuSigned by:

Mari Kaada

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Corporate Director Q&R

Laerdal Medical AS

01.02.2021



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