



EU DECLARATION OF CONFORMITY

Responsible Manufacturer:	Laerdal Medical AS P.O. Box 377 Tanke Svilandsgate 30 4002 Stavanger Norway
Manufacturing site:	Laerdal Medical (Suzhou) Co. Ltd. Building 18,19,20, No.57 Huoju Road, SND, Suzhou, Jiangsu Province 215009, China
Product Name:	Laerdal Compact Suction Unit 4 (LCSU 4)
Product Options:	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) 881151 LCSU 4, Replacement unit 881152 LCSU 4, RTCA, Replacement unit

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), as amended by EU 2015/863.

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 Product Assurance AS to ISO 13485:2016.

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

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Adrienne Farrington

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Adrienne Farrington,
Regulatory Affairs Specialist

Stavanger, Norway
09th October 2025