

CERTIFICATE OF ASSESSMENT - EC

DET NORSKE VERITAS

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Social Affairs.

Certificate No.: 8820-2007-CE-NOR

This is to certify that the Quality System for the product group:

Laerdal Silicone Resuscitators

- defined by manufacturer as Class IIa devices -

Manufactured by

Laerdal Medical AS

P.O. Box 377, Tanke Svilandsgate 30, 4002 Stavanger, Norway

complies with the applicable requirements of the Directive.

The quality system for these products has been assessed according to the procedure of conformity assessment described in Article 11.3.a) and Annex II (excl. section 4). Identification of the products covered by this certificate is given in the Appendix.

Limitations:

The manufacturer must inform Det Norske Veritas Certification AS of any plan for significant changes to the quality system. Annual Periodical Audits will be held to verify the validity of this Certificate.

Hovik, 21 September 2007

for Det Norske Veritas Certification AS

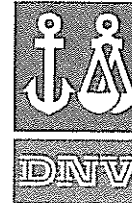
SK Steinar Kristensen
Head of section,
Product Certification

CE
0434

Valid until: 21 September 2012

for Cecilie Gudesen Torp
Senior engineer

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC



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APPENDIX

Appendix to Certificate No.: 8820-2007-CE-NOR
Manufacturer: Laerdal Medical AS
Product group: Laerdal Silicone Resuscitators


The Certificate referred to above covers the following devices:

- **Laerdal Silicone Resuscitator (Adult), 87xxxx**
- **Laerdal Silicone Resuscitator (Paediatric), 86xxxx**
- **Laerdal Silicone Resuscitator (Preterm), 85xxxx**
- **Accessories**
 - **Silicone extension tube (28 cm), 871000**
 - **Manometer connector, 850900**
 - **Expiration diverter (OD 30 mm), 850500**
 - **Intake Valve Adapter (23 mm OD), 531907**
 - **Silicone Mask No. 2, 851700**
 - **Silicone Mask No.0/1, 851600**
 - **Silicone Mask No.00, 851500**
 - **Silicone Child Mask Cover 3-4 w/Multi Function Mask Cover, 860220**
 - **Multi Function Mask Cover 3-4, 865200**
 - **Multi Function Mask Cover 4-5, 875200**
 - **Silicone Child Mask Cover 4-5 w/Multi Function Mask Cover, 870220**
 - **Head Strap w/ attachment ring, 870400**
 - **Hanging loop, 870120**

The complete list of devices is filed with Notified Body ref., project number PRJC-17486-2007-PRC-NOR

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21 September 2007


for Cecilie Gudesen Torp





DECLARATION OF CONFORMITY

Responsible Manufacturer: Laerdal Medical AS
Tanke Svilandsgate 30
4007 Stavanger
Norway

Product Name: **Laerdal Silicone Resuscitator**

Product Options:

87xxxx	Laerdal Silicone Resuscitator (Adult)
86xxxx	Laerdal Silicone Resuscitator (Paediatric)
85xxxx	Laerdal Silicone Resuscitator (Preterm)

Accessories:

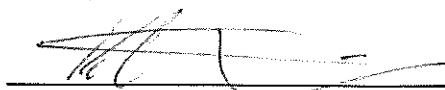
871000	Silicone extension tube (28 cm)
850900	Manometer connector
850500	Expiration diverter (OD 30 mm)
531907	Intake Valve Adapter (23 mm OD)
851700	Silicone mask No.2
851600	Silicone mask No.0/1
851500	Silicone mask No.00
860220	Silicone child mask 3-4 w/Multi Funct. Mask Cover
865200	Multi Function Mask Cover 3-4
875200	Multi Function Mask Cover 4-5
870220	Silicone child mask 4-5 w/Multi Funct. Mask Cover
870400	Head strap w/ attachment, ring
870120	Hanging Loop

to which this declaration relates is in conformity with Annex I – Essential Requirements of the **Council Directive 93/42/EEC for Medical Devices**. All supporting documentation is retained by the manufacturer.

Classification: The product is Class IIa according to rule 2 of Annex IX.

Laerdal Medical AS is certified by Det Norske Veritas, DNV, to ISO13485:2003. Conformity Assessment is based on the principles described in Annex II of the Directive 93/42/EEC.

Stavanger, 11 September 2007



Kenneth Lubcke
Product Manager

