



# 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 N°.: 6469-2007-CE-NOR**

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

### **Respiratory Care Medical Devices**

- defined by manufacturer as Class IIa devices -

*Manufactured by*

**Polymed (Xiamen) Plastic Industrial Co., Ltd.**

Unit B, 1~5F, Block G, Warehouse & Process Complex Building Xiangyu F.T.Z., Xiamen, China

**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 11.2.b) and Annex V** Identification of the products covered by this certificate is given in the Appendix.

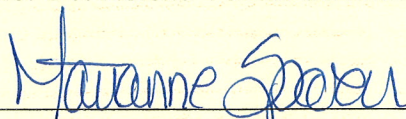
#### **Limitations:**

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.

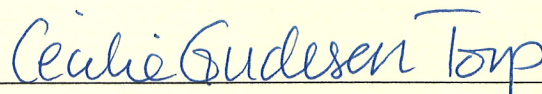
*Høvik, 14 August 2007*

*Valid until: 14 August 2012*

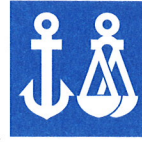
for Det Norske Veritas Certification AS

  
Marianne Spæren  
Head of section,  
Product Certification

**CE**  
**0434**

  
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*

**CERTIFICATE OF ASSESSMENT - EC****APPENDIX**

**Appendix to Certificate No.:** 6469-2007-CE-NOR  
**Manufacturer:** Polymed (Xiamen) Plastic Industrial Co., Ltd.  
**Product group:** Respiratory Care Medical Devices

The Certificate referred to above covers the following devices:

- **Resuscitator Unit**
  - RUGU01/RUGU02
  - RUGH01/RUGH02
- **Pocket Mask**
  - RCGU02
- **Rescue pump**
  - 1.VSP.AMB.276001
- **Infant Disposable mask with inflation valve**
  - I.CUS.MAR.200900
- **Paediatric Disposable mask with inflation valve**
  - I.CUS.MAR.200850
- **Child Disposable mask with inflation valve**
  - I.CUS.MAR.200800
- **Adult small Disposable mask with inflation valve**
  - I.CUS.MAR.200750V
- **Adult Disposable mask with inflation valve**
  - I.CUS.MAR.200700
- **Paediatric Personal mask**
  - I.CON.MAR.2202025PB

The complete list of accessories is filed with the Notified Body, project number PRJC-11585-2007-PRC-RGC

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14 August 2007

Cecilie Gudesen Torp

