# DET NORSKE VERITAS

## PRODUCTION QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 18462-2008-CE-NOR Rev.
This Certificate consists of 4 pages

*This is to certify that the Quality Management System of*

**Marshall Products Ltd**

Bath, United Kingdom

*for the manufacture, production and final product inspection/testing of*

Airway Management and Anaesthetic Equipment
Medical Devices

*has been assessed with respect to*
the conformity assessment procedure described in Article 11.2.b and Annex V (Module D1)
of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*
Høvik, 28 April 2008

*This Certificate is valid until:*
**28 April 2013**

*For* DET NORSKE VERITAS CERTIFICATION AS
Norway

Steinar Kristensen
*Certification Manager*

Notified Body No.:
0434

Jenny Helen Nytun
*Technical Reviewer*

## Jurisdiction

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

## Certificate history

| Revision | Description | Issue Date |
|---|---|---|
| 1.0 | Original Certificate – Re-Certification | **2008-04-28** |

## Products covered by this Certificate

| Product Description | Product | | Class |
|---|---|---|---|
| Reusable Manual Resuscitators and Face Masks | | Reusable Large Volume Adult Manual Resuscitator<br>Reusable Adult Manual Resuscitator<br>Reusable Child Manual Resuscitator<br>Reusable Infant Manual Resuscitator | IIa |
| | 200300<br>200200<br>200100 | Reusable Contour Face Mask Size 3<br>Reusable Contour Face Mask Size 4<br>Reusable Contour Face Mask Size 5 | |
| | 200600<br>200500<br>200400 | Reusable Silicone Face Mask Size 0<br>Reusable Silicone Face Mask Size 1<br>Reusable Silicone Face Mask Size 2 | |
| | 100400<br>120400<br>100300<br>101102<br>101101<br>101100<br>110300 | Reusable Patient Intake Valve Adult/ Child<br>Reusable Patient Intake Valve Infant<br>Reusable Patient Valve Adult/ Child<br>Disposable Oxygen Tubing<br>Disposable Reservoir Bag Infant<br>Disposable Reservoir Bag Adult/ Child<br>Pressure Limitation Valve | |
| | 101110 | Reusable Manual Resuscitator PEEP Valve | |
| Single Use Manual Resuscitators and Face Masks | | Disposable Large Volume Adult Manual Resuscitator<br>Disposable Adult Manual Resuscitator<br>Disposable Child Manual Resuscitator<br>Disposable Infant Manual Resuscitator | IIa |
| | | PVC Disposable Large Volume Adult Manual Resuscitator<br>PVC Disposable Adult Manual Resuscitator<br>PVC Disposable Child Manual Resuscitator<br>PVC Disposable Infant Manual Resuscitator | |
| | 200600D<br>200500D<br>200400D | Disposable Silicone Face Mask Size 0<br>Disposable Silicone Face Mask Size 1<br>Disposable Silicone Face Mask Size 2 | |

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|---|---|---|---|
| | 200950V | Disposable Cushion Face Mask Size 0 | |
| | 200900V | Disposable Cushion Face Mask Size 1 | |
| | 200850V | Disposable Cushion Face Mask Size 2 | |
| | 200800V | Disposable Cushion Face Mask Size 3 | |
| | 200750V | Disposable Cushion Face Mask Size 4 | |
| | 200700V | Disposable Cushion Face Mask Size 5 | |
| | 101120 | Disposable Manual Resuscitator PEEP Valve | |
| Personal Masks | 2102025CC | Disposable Adult/ Child Personal Mask in carry case | IIa |
| | 2102025PB | Disposable Adult/ Child Personal Mask in polythene bag | |
| | 2103025CC | Disposable Paediatric Personal Mask | |
| | 2102050 | Personal Mask One Way Filter | |
| Standard Laryngeal Masks | 777100 | Silicone Single Use Laryngeal Airway Device Size 1 | IIa |
| | 777150 | Silicone Single Use Laryngeal Airway Device Size 1.5 | |
| | 777200 | Silicone Single Use Laryngeal Airway Device Size 2 | |
| | 777250 | Silicone Single Use Laryngeal Airway Device Size 2.5 | |
| | 777300 | Silicone Single Use Laryngeal Airway Device Size 3 | |
| | 777400 | Silicone Single Use Laryngeal Airway Device Size 4 | |
| | 777500 | Silicone Single Use Laryngeal Airway Device Size 5 | |
| | 700100 | Reusable Laryngeal Airway Device Size 1 | |
| | 700150 | Reusable Laryngeal Airway Device Size 1.5 | |
| | 700200 | Reusable Laryngeal Airway Device Size 2 | |
| | 700250 | Reusable Laryngeal Airway Device Size 2.5 | |
| | 700300 | Reusable Laryngeal Airway Device Size 3 | |
| | 700400 | Reusable Laryngeal Airway Device Size 4 | |
| | 700500 | Reusable Laryngeal Airway Device Size 5 | |
| | 707100 | PVC Single Use Laryngeal Airway Device Size 1 | |
| | 707150 | PVC Single Use Laryngeal Airway Device Size 1.5 | |
| | 707200 | PVC Single Use Laryngeal Airway Device Size 2 | |
| | 707250 | PVC Single Use Laryngeal Airway Device Size 2.5 | |
| | 707300 | PVC Single Use Laryngeal Airway Device Size 3 | |
| | 707400 | PVC Single Use Laryngeal Airway Device Size 4 | |
| | 707500 | PVC Single Use Laryngeal Airway Device Size 5 | |
| Nasopharyngeal Airways | 300306 | Nasopharyngeal Airway Size 6 | IIa |
| | 300307 | Nasopharyngeal Airway Size 7 | |
| | 300308 | Nasopharyngeal Airway Size 8 | |
| | 300309 | Nasopharyngeal Airway Size 9 | |
| Resuscitation Circuits | 800100/PINK | Disposable Pink Neonatal Resuscitation PEEP Circuit 1m | IIa |
| | 800100/BLUE | Disposable Blue Neonatal Resuscitation PEEP Circuit 1m | |
| | 800150/PINK | Disposable Pink Neonatal Resuscitation PEEP Circuit 1.5m | |
| | 800150/BLUE | Disposable Blue Neonatal Resuscitation PEEP Circuit 1.5m | |
| | 800201 | Soft Adapter accessory for use with Neonatal Resuscitation PEEP Circuit | |
| | 800200 | Manometer Line accessory for use with Neonatal Resuscitation PEEP Circuit | |

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|---|---|---|---|
| **Flexible Laryngeal Masks** | **777200FLEX** | **Silicone Single Use Flexible Laryngeal Airway Device Size 2** | **IIa** |
| | **777250FLEX** | **Silicone Single Use Flexible Laryngeal Airway Device Size 2.5** | |
| | **777300FLEX** | **Silicone Single Use Flexible Laryngeal Airway Device Size 3** | |
| | **777400FLEX** | **Silicone Single Use Flexible Laryngeal Airway Device Size 4** | |
| | **777500FLEX** | **Silicone Single Use Flexible Laryngeal Airway Device Size 5** | |
| | **700200FLEX** | **Reusable Flexible Laryngeal Airway Device Size 2** | |
| | **700250FLEX** | **Reusable Flexible Laryngeal Airway Device Size 2.5** | |
| | **700300FLEX** | **Reusable Flexible Laryngeal Airway Device Size 3** | |
| | **700400FLEX** | **Reusable Flexible Laryngeal Airway Device Size 4** | |
| | **700500FLEX** | **Reusable Flexible Laryngeal Airway Device Size 5** | |
| | **707200FLEX** | **PVC Single Use Flexible Laryngeal Airway Device Size 2** | |
| | **707250FLEX** | **PVC Single Use Flexible Laryngeal Airway Device Size 2.5** | |
| | **707300FLEX** | **PVC Single Use Flexible Laryngeal Airway Device Size 3** | |
| | **707400FLEX** | **PVC Single Use Flexible Laryngeal Airway Device Size 4** | |
| | **707500FLEX** | **PVC Single Use Flexible Laryngeal Airway Device Size 5** | |

## Sites covered by this certificate

| Site Name | Address |
|---|---|
| Marshall Products Ltd | 1 The Maltings, BA1 3JL, Bath, United Kingdom |

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE