

## Production Quality Assurance

No. CE 72113



Issued to:

**RAWCAR Group LLC,  
dba Contour Fabricators Inc.,  
dba CFI Medical Solutions  
14241 Fenton Road  
Fenton  
Michigan  
48430  
USA**

In respect of:

**Those aspects of Annex V related to securing and maintaining sterility in the manufacture of general equipment covers and urology drains**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David Ford, Director, Healthcare and Testing Services

First Issued: 7 Apr 2003

Date: 21 Jul 2009

Expiration Date: 6 Apr 2013

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### Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 72113**  
Date: **21 Jul 2009**  
Issued to: **RAWCAR Group LLC, dba Contour Fabricators Inc., dba CFI Medical Solutions**  
**Fenton**  
**USA**

### Subcontractor

### Service(s) supplied

Centurion Sterilization Services  
(Tri-State Hospital Supply Corp.)  
301 Catrell Drive  
Howell  
MI 48843  
USA

ETO Sterilization

## History of Quality Assurance Certificate

**Certificate No:** CE 72113  
**Issue Date:** 21 July 2009  
**Issued to:** Contour Fabricators Inc.  
Fenton  
USA

Date	Reference Number	Action
07 April 2003	4414764	First issue
14 April 2008	7199499	Certificate renewal
21 July 2009	7430871	Name change from Contour Fabricators to RAWCAR Group LLC, dba Contour Fabricators Inc., dba CFI Medical Solutions