



Certificate

Production Quality Assurance

No. CE 542485



Issued to:

Neogenix, LLC dba Ogenix
3401 Enterprise Pkwy, Suite 340
Beachwood
Ohio
44122
USA

In respect of:

Manufacture of oxygen therapy equipment and sterile cannula for wound treatment

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 BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **18 Feb 2009**

Date: **16 Jan 2014**

Expiration Date: **17 Feb 2019**

Page: 1 of 1

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.

...making excellence a habit.™



List of Significant Subcontractors

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

Certificate No. **CE 542485**
Date: **16 Jan 2014**
Issued to: **Neogenix, LLC dba Ogenix**
Beachwood
USA

| Subcontractor | Service(s) supplied |
|---|---------------------|
| Medical Device Safety Service GmbH Schiffgraben 41 D-30175 Hannover Germany | EU Representative |
| Sparton Medical Systems 22740 Lunn Road Strongsville Ohio 44149 USA | Manufacture |
| Excel Medical Products, Inc. 3145 Copper Avenue Fenton Michigan 48430 USA | Manufacture |
| Centurion Sterilization Services A Division of Centurion Medical Pro 301 Catrell Drive Howell Michigan 48843 USA | ETO Sterilization |



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| OMARC, LLC 588 Pleasant Street, Unit #2 Norwood Massachusetts 02062 USA | Manufacture |



History of Quality Assurance Certificate

Certificate No: **CE 542485**
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| Date | Reference Number | Action |
|------------------|------------------|--|
| 18 February 2009 | 7280977 | First issue |
| 24 February 2010 | 7481685 | The addition of Ogenix Corporation in Norwood for manufacturing and Medical Device Safety Service as EU-Representative. Change of name from Ogenix Corp. into OMARC, LLC |
| 30 January 2012 | 7752809 | Change of company name from Ogenix Corporation to Neogenix, LLC dba Ogenix. Relocation from Chagrin Boulevard (Beachwood) to Enterprise Pkwy (Beachwood). |
| 16 January 2014 | 8084002 | Certificate renewal |