

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 610241  
**Issued To:** **O2 Concepts**  
**199 Park Road Extension**  
**Suite B**  
**Middlebury**  
**Connecticut**  
**06762**  
**USA**

In respect of:

**Design and manufacture of oxygen concentrators.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-06-09**

Date: **2020-04-01**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

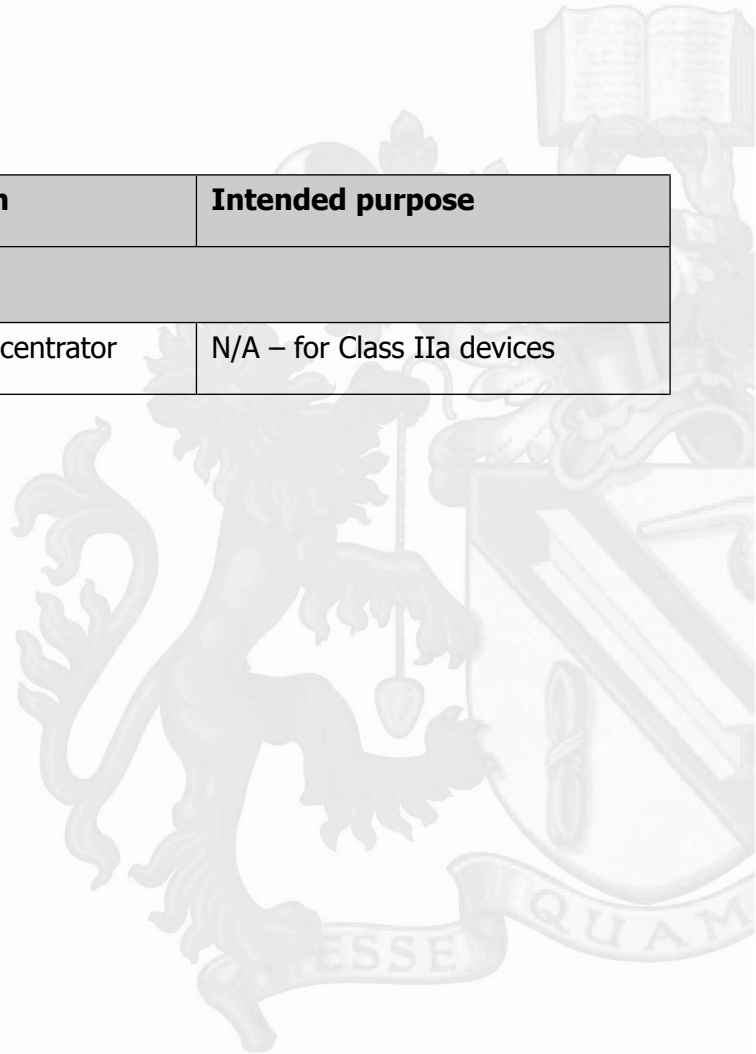
# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 610241

Issued To:

**O2 Concepts  
199 Park Road Extension  
Suite B  
Middlebury  
Connecticut  
06762  
USA**

NBOG code(s)	Device description	Intended purpose
<b>Class IIa</b>		
MD 1102, MDS 7010	Portable oxygen concentrator	N/A – for Class IIa devices



First Issued: **2015-06-09**

Date: **2020-04-01**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

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

Certificate No: **CE 610241**  
Date: **2020-04-01**  
Issued To: **02 Concepts**  
**199 Park Road Extension**  
**Suite B**  
**Middlebury**  
**Connecticut**  
**06762**  
**USA**

**Subcontractor:**

**Service(s) supplied**

MT Promedt Consulting GmbH  
Altenhofstrasse 80  
66386 St. Ingbert  
Germany

**EU Representative**

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

**Certificate No:** CE 610241  
**Date:** 2020-04-01  
**Issued To:** O2 Concepts  
 199 Park Road Extension  
 Suite B  
 Middlebury  
 Connecticut  
 06762  
 USA

Date	Reference Number	Action
09 June 2015	8107195	First Issue.
07 April 2017	8633124	Change of address from "15 Commerce Road, Newtown CT 06470 USA" to "199 Park Road Extension Suite B, Middlebury, CT 06762 USA." Removal of "Dual mode portable," from scope of certificate.
04 February 2019	8787027	Traceable to NB 0086.
Current	9769985	Certificate renewal. Addition of device table.

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.  
 This certificate was issued electronically and is bound by the conditions of the contract.