



Gas Control Equipment

EC Declaration of Conformity **under Annex II of Medical Device Directive**

Manufacturer
Gas Control Equipment Ltd, 100 Empress Park, Penny Lane, Haydock, St Helens, Merseyside WA11 9DB United Kingdom

CERTIFICATE NUMBER **10000321467-PA-NA-CZE Rev. 2.0**

I, the undersigned Management Representative of:

Gas Control Equipment Ltd,
100 Empress Park, Penny Lane, Haydock,
St Helens, Merseyside WA11 9DB
United Kingdom

after having verified the completeness and correctness of the required technical documentation,

hereby declare

under our sole responsibility and authority that the Zen-O Portable Oxygen Concentrator (Class IIa) and the Zen-O Lite Portable Oxygen Concentrator (Class IIa), listed below, meet the applicable provisions of the Medical Device Directive (Council Directive 93/42/EEC, OJ L 169, 12.7.1993, as amended by M5) Annex I - Essential Requirements, and has been subjected to the conformity procedures laid down in Annex II – Full Quality Assurance System, under the supervision of DNV Product Assurance AS a Notified Body authorized by the Norway Competent Authority, and carrying the Notified Body Number 2460, and therefore can bear the CE Marking, in accordance with Article 17.

Ref#	Description
RS-00500	Zen-O Portable Oxygen Concentrator (POC contained in shipping Assemblies, RS-00502-G-S and RS-00502-G-D)
RS-00500C	Zen-O Portable Oxygen Concentrator with Clarity (POC contained in shipping Assemblies, RS-00502C-G-S and RS-00502C-G-D)
RS-00600	Zen-O Lite Portable Oxygen Concentrator (POC contained in shipping Assemblies, RS-00608-G-S and RS-00608-G-D)
RS-00600C	Zen-O Lite Portable Oxygen Concentrator (POC contained in shipping Assemblies, RS-00608-CG-S and RS-00608-CG-D)

Declaration of Conformity to EU RoHS 2

GCE, Ltd. declares that, to the best of our knowledge, all electrical and electronic equipment (EEE) sold by the company are in compliance with Annex II of the European Directive (EU) 2011/65/EU for control of lead, cadmium, hexavalent chromium, mercury, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE) (also known as "**RoHS 2 Recast**") and conform to the requirements of Module A of the DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 09 JUL 2008.

In addition, this Declaration of Conformity is issued under the sole responsibility of GCE. Specifically, products manufactured do not contain the substances listed below in concentrations greater than the listed maximum value.

The following Maximum Concentration Limits (MCVs) apply:

- Lead (Pb) 0.1 % by weight = 1000 mg/kg = 1000 ppm
- Mercury (Hg) 0.1 % by weight = 1000 mg/kg = 1000 ppm
- Cadmium (Cd) 0.01 % by weight = 100 mg/kg = 100 ppm
- Chromium VI (Cr VI) 0.1 % by weight = 1000 mg/kg = 1000 ppm
- PBB 0.1 % by weight = 1000 mg/kg = 1000 ppm
- PBDE 0.1 % by weight = 1000 mg/kg = 1000 ppm

Declaration of Conformity to EU RED – RS-0500C

GCE, Ltd. declares that, to the best of our knowledge, the Zen-O Portable Oxygen Concentrator with Clarity, RS-00500C listed above, is in compliance with the Radio Equipment Directive 2014/53/EU (also known as “RED”). The following harmonised standards and technical specifications have been applied:

Title, Date of standard/specification:

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2:2014 (edition 4.0), EN 60601-1-2:2015
Spectrum for wideband transmission systems in 2.4GHz ISM band	EN 300 328 v2.1.1
Global System for Mobile communications (GSM); Mobile Stations (MS) equipment;	EN 300 511 V12.5.1
Satellite Earth Stations and Systems (SES); Global Navigation Satellite System (GNSS) receivers; Radio equipment operating in the 1 164 MHz to 1 300 MHz and 1 559 MHz to 1 610 MHz frequency bands;	EN 303 413 V1.1.0
ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements;	The below all referencing EN 301 489-1 V2.2.0, EN 301 489-3 V2.1.1, EN 301 489-7 V1.3.1, EN 301 489-17 V3.2.0, EN 301 489-19 V2.1.0 EN 301 489-52 V1.1.0
Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)	EN 62311:2008

Notified body:

Element Materials Technology Portland – Evergreen Inc

Notified body number:

0981

Certificate Number EMT18RED1106 V1

Intervention of notified body - EU-Type Examination

Declaration of Conformity to EU RED – RS-00600C

GCE, Ltd. declares that, to the best of our knowledge, the Zen-O lite Portable Oxygen Concentrator with Clarity, RS-00600C listed above, is in compliance with the Radio Equipment Directive 2014/53/EU (also known as “RED”). The following harmonised standards and technical specifications have been applied:

Title, Date of standard/specification:

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2:2014 (edition 4.0), EN 60601-1-2:2015
Spectrum for wideband transmission systems in 2.4GHz ISM band	EN 300 328 v2.1.1
Global System for Mobile communications (GSM); Mobile Stations (MS) equipment;	EN 300 511 V12.5.1
IMT Cellular Networks; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU;	EN 301 908-1 V11.1.1 EN 301 908-2 V11.1.2 EN 301 908-13 V11.1.2
Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment	EG 203 367 V1.1.1 (2016-06)
Satellite Earth Stations and Systems (SES); Global Navigation Satellite System (GNSS) receivers; Radio equipment operating in the 1 164 MHz to 1 300 MHz and 1 559 MHz to 1 610 MHz frequency bands;	EN 303 413 V1.1.1
ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements;	The below all referencing EN 301 489-1 V2.2.0, EN 301 489-3 V2.1.1, EN 301 489-7 V1.3.1, EN 301 489-17 V3.2.0, EN 301 489-19 V2.1.0 EN 301 489-52 V1.1.0
Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)	EN 62311:2008

Notified body:

Element Materials Technology Portland

Certificate Number ENW20RED1065

Intervention of notified body –

EU-Type Examination against Article 3.2

Notified body number:

0981

Relocation of GCE Production

The above information has been reviewed and will be unaffected by the relocation of GCE's UK production to the GCE facility in the Czech Republic in January 2021.

Manufacturing sites

GCE s.r.o., Zizkova 381, 583 01 Chotebor, Czech Republic.

Victor Equipment de Mexico S.A. de C.V. Jesus Siqueiros #652, 83170 Hermisillo, Mexico.

EU Authorised Representative

GCE s.r.o. are the EU authorised representative for GCE Ltd

GCE, s.r.o.,
Zizkova 381, 583 01
CHoteobor,
Czech Republic.

Signed:

Steve Nelson



Date of Issue

17/05/2021

Quality and Regulatory Affairs Manager

Place of Issue

Haydock, UK

Revision Record:

Revision	Date	Author	Change Description
1	1-10-2015	Steve Nelson	Initial release.
2	24-11-2015	Steve Nelson	Change of Annex No. in the title
3	27-6-2016	Steve Nelson	Addition of Zen-O Lite
4	5-8-2016	Steve Nelson	Addition to Descriptions
5	23-2-2017	Steve Nelson	Change of address format to match QMS Certificate
6	11-6-2018	Steve Nelson	Addition of Zen-O Clarity
7	21/12/2018	Will Turner	Addition of Zen-O Clarity Standards
8	21/8/2018	Chris Phillips	Addition of Zen-O lite Clarity
9	18-9-2019	Chris Phillips	Change of Notified Body from LR to Presafe
10	31-10-2019	Chris Phillips	Change of Notified Body from Element UK to US
11	13-5-2020	Chris Phillips	Addition of Zen-O lite Clarity RED
12	21-12-2020	Chris Phillips	Addition of no change statement for production move
13	12-02-2021	Steve Nelson	Addition of GCE sro as authorised representative
14	10-5-2021	Michael Shaw	DNV name change, Cert No change. Add manufacturing sites.

