

EU DECLARATION OF CONFORMITY

Document ID: REG-00079 Rev17 - TF15-030-09-01

Manufacturer 's Name: Gas Control Equipment Limited

Manufacturer 's Address: 100 Empress Park, Penny Lane, Haydock, St Helens,
WA11 9DB, UK

SRN (Single Registration Number): N/A

Authorized Representative Name: GCE, s.r.o.

Authorized Representative Address: Žižkova 381, 583 01, Chotěboř, Czech Republic

Product Group: Portable oxygen concentrators

Name of the Device: **Zen-O, Zen-O Clarity, Zen-O Lite including Arya, and Zen-O Lite Clarity**

Risk Classification: IIa, according to rule 11

GMDN code: 31321

Standards / Common specification:

Applicable to RS-00500/RS-00500C

EN 301 489-1 V2.2.0	IEC 60601-1-2:2014 (edition 4.0)
EN 301 489-3 V2.1.1	EN 60601-1-2:2015
EN 301 489-7 V1.3.1	EN 300 328 v2.1.1
EN 301 489-17 V3.2.0	EN 300 511 V12.5.1
EN 301 489-19 V2.1.0	EN 303 413 V1.1.0
EN 301 489-52 V1.1.0	EN 62311:2008

Applicable to RS-00600/RS-00600C

EN 301 489-1 V2.2.0	IEC 60601-1-2:2014 (edition 4.0)
EN 301 489-3 V2.1.1	EN 60601-1-2:2015
EN 301 489-7 V1.3.1.	EN 300 328 v2.1.1
EN 301 489-17 V3.2.0	EN 300 511 V12.5.1
EN 301 489-19 V2.1.0	EN 301 908-1 V11.1.1
EN 301 489-52 V1.1.0	EN 301 908-2 V11.1.2
	EN 301 908-13 V11.1.2
	EG 203 367 V1.1.1 (2016-06)
	EN 303 413 V1.1.1
	EN 62311:2008

Notified Body name: DNV Product Assurance AS

Notified Body Address: Veritasveien 3, N-1363 Høvik, Norway

Notified Body Identification number: 2460

EC Certificate Number: 10000321467-PA-NA-CZE Rev. 2.0



Gas Control Equipment

Gas Control Equipment Limited, 100 Empress Park, Penny Lane, Haydock, St Helens, WA11 9DB, United Kingdom, tel.: +44 1942 292950, VAT: 02003134,
e-mail: gce@gcegroup.com
www.gcegroup.com

Template number GR 2.02.10 T2 version 1.03

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Conformity assessment route:

This declaration of conformity is issued under the sole responsibility of Gas Control Equipment Limited. We hereby declare that the medical device(s) specified above meet the provision of the Regulation MDD 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by DNV Product Assurance AS.

The product is in accordance with Annex II (excluding section 4) of the MDD 93/42/EEC and is safe for declared purpose of use under standard conditions. Any modification to the product, not authorized by us, will invalidate this declaration.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

A handwritten signature in blue ink, appearing to be 'MS', with a faint 'Copyright ©' watermark below it.

Place and date of issue:

Haydock 10/10/2023

On behalf of manufacturer signed by Michael Shaw.

Person responsible for regulatory compliance

Note: List of variants is in attachment of this document.



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LIST OF VARIANTS

Annex of EU Declaration of conformity with Document ID: REG-00079 Rev16 - TF15-030-09-01

Product group: Mobile/ Portable Oxygen Concentrator

Name of the device: Zen-O

List of variants:

REF number	Variant name
RS-00500	Zen-O Portable Oxygen Concentrator
RS-00500C	Zen-O Portable Oxygen Concentrator with Clarity

Product group: Mobile/ Portable Oxygen Concentrator

Name of the device: Zen-O lite

List of variants:

REF number	Variant name
RS-00600	Zen-O lite Portable Oxygen Concentrator <i>Includes branded devices as "Arya" for the customer First Class Medical</i>
RS-00600C	Zen-O lite Portable Oxygen Concentrator with Clarity

Date of issue of the annex: 25/05/2021

Version of the annex: 17



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