NIDEK Medical

Manufacturer:
Nidek Medical Products, Inc.
3949 Valley East Industrial Drive
Birmingham, AL 35217 USA

EC REP

EU Representative:
mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany

Declaration of Conformity

We hereby declare, under our sole responsibility, that the CE marked products listed hereafter are covered by the **"EC Marking of Conformity Certificate", certificate number: 41312638-02, effective on 23 October 2018 and delivered by Intertek Semko AB, Kista, Sweden, Notified Body Identification Number 0413**, and conform to the requirements of **Annex II in Council Directive 93/42/EEC of 14 June 1993**, concerning medical devices and further conform to **Swedish regulation LVFS 2003:11.**

Regulations / Standards Applied:

Risk Class:	IIa according to Annex IX, Rule 11	**Reach:**	Regulation (EC) No 1907/2006
Electrical Safety:	EN 60601-1:2006 + A1:2013	**ROHS:**	Directive 2011/65/EU
EMC:	EN 60601-1-2: 2015	**Packaging:**	Directive 94/62/EC
Usage Safety:	EN ISO 80601-2-69: 2014	**WEEE:**	2012/92/EU
Quality System:	EN 13485:2016 Certified by Intertek Semko Certificate# 0070049-01 effective 19 Oct 2018		

This Declaration of Conformity covers "**Oxygen Concentrators GMDN 12873**" as specified in the following Product List:

Ref no:	Description	UDI-DI
905	Mark 5 Nuvo	00038214000004
905NI	Mark 5 Nuvo	00038214000363
925	Mark 5 Nuvo Lite	00038214000035
925UK	Mark 5 Nuvo Lite	00038214001179
925DP	Mark 5 Nuvo Lite	00038214001094
925/60	Mark 5 Nuvo Lite	00038214000431
925/60UK	Mark 5 Nuvo Lite	00038214001285
925NEB	Mark 5 Nuvo Lite	00038214000882
925-IS	Mark 5 Nuvo Lite	00038214000066
925GC	Mark 5 Nuvo Lite	00038214000929
925GCUK	Mark 5 Nuvo Lite	00038214001568
925BMC	Mark 5 Nuvo Lite	00038214001513
925-OCSI	Mark 5 Nuvo Lite	00038214001520
925Q	Mark 5 Nuvo Lite	00038214000974
935	Mark 5 Nuvo Lite 3	00038214000080
935/60	Mark 5 Nuvo Lite 3	00038214001407
985	Mark 5 Nuvo 8	00038214000233

Ref no:	Description	UDI-DI
985UK	Mark 5 Nuvo 8	00038214001193
985DP	Mark 5 Nuvo 8	00038214001087
985GC	Mark 5 Nuvo 8	00038214001124
985GCUK	Mark 5 Nuvo 8	00038214001551
985NI	Mark 5 Nuvo 8	00038214001544
1005	Mark 5 Nuvo 10	00038214001360
1005UK	Mark 5 Nuvo 10	00038214001469
1005GC	Mark 5 Nuvo 10	00038214001599
1005GCUK	Mark 5 Nuvo 10	00038214001575
1005NI	Mark 5 Nuvo 10	00038214001605
1005/60UK	Mark 5 Nuvo 10	00038214001728
3005	Max 30	00038214001636
3005AU	Max 30	00038214001766
3005IS	Max 30	00038214001896
3005UK	Max 30	00038214001742
3010	Max 30	00038214001643
3010UK	Max 30	00038214001988

Authorized on 25 October 2018 for all devices manufactured hereafter by:

Name of Authorized Signatory: Joseph M. Krawczyk
Position Held in Company: President and Chief Executive Officer

Signature

NIDEK MEDICAL PRODUCTS, INC. CORPORATE SEAL 1986 ALABAMA

ORIGINAL