NIDEK Medical

Declaration of Conformity

Manufacturer	Nidek Medical Products, Incorporated
Address:	3949 Valley East Industrial Drive Birmingham, Alabama, 35217 USA
Represented by:	mdi Europa GmbH Langenhagener Str. 71 D-30855 Langenhagen Germany
Declares that devices:	
Names:	Mark5 Nuvo8 Oxygen Concentrators
Model Number(s):	985 & 985GR

To which this declaration relates are in conformity with LVSF 2003:11, the Swedish implementation of the European Medical Devices Directive (MDD) 93/42/EEC as amended by LVFS 2009:18 implementation of European Directive 2007/47/EC.

These devices are Classified as:

MDD:	II(a)	According to rule 11
Electrical Safety	Class II	
Degree of Protection	Type B	

Authorized on 1 February 2010 for all devices manufactured hereafter by:

Name of Authorized Signatory:	Anand Chitlangia
Position Held in Company	President and Chief Executive Officer
Signature	A Chitlangi

14 Sept 2010

M. Sander-Giesen

Form Number DOC2010/02
2010-9251DOC Rev A

NIDEK Medical

Declaration of Conformity

Manufacturer	Nidek Medical Products, Incorporated
Address:	3949 Valley East Industrial Drive Birmingham, Alabama, 35217 USA
Represented by:	mdi Europa GmbH Langenhagener Str. 71 D-30855 Langenhagen Germany
Declares that devices:	
Names:	Mark5 Nuvo Oxygen Concentrators
Model Number(s):	Mark 5 Nuvo (M5C5) Series – 905, 905SP, 905-003, 905-003ASV, 905-003 NEB, 905-003NEBQV, 905-003Q, 905-003QV, 905-003TF, 905-003TFSV & 905-003VI;

To which this declaration relates are in conformity with LVSF 2003:11, the Swedish implementation of the European Medical Devices Directive (MDD) 93/42/EEC as amended by LVFS 2009:18 implementation of European Directive 2007/47/EC.

These devices are Classified as:

MDD:	II(a)	According to rule 11
Electrical Safety	Class II	
Degree of Protection	Type B	

Authorized on 1 February 2010 for all devices manufactured hereafter by:

Name of Authorized Signatory:	Anand Chitlangia
Position Held in Company	President and Chief Executive Officer

Signature A Chitlangia

14 Sept 2010

M. Sauder-Grisson

Form Number DOC2010/02
2010-2224DOC Rev B

NIDEK Medical

Declaration of Conformity

Manufacturer Address:	Nidek Medical Products, Incorporated 3949 Valley East Industrial Drive Birmingham, Alabama, 35217 USA
Represented by:	mdi Europa GmbH Langenhagener Str. 71 D-30855 Langenhagen Germany
Declares that devices:	
Names:	Mark5 Nuvo Lite Oxygen Concentrators
Model Number(s):	Mark5 Nuvo Lite Series - 925, 925FR, 925GR, 925GC, 925HK, 925NEB, 925NEB-VI, 925Q, 925/60 & 925/60K

To which this declaration relates are in conformity with LVSF 2003:11, the Swedish implementation of the European Medical Devices Directive (MDD) 93/42/EEC as amended by LVFS 2009:18 implementation of European Directive 2007/47/EC.

These devices are Classified as:

MDD:	II(a)	According to rule 11
Electrical Safety	Class II	
Degree of Protection	Type B	

Authorized on 1 February 2010 for all devices manufactured hereafter by:

Name of Authorized Signatory:	Anand Chitlangia
Position Held in Company	President and Chief Executive Officer
Signature	

14 Sept 2010

Form Number DOC2010/02
2010-8400DOC Rev B

Certificate of CE-Registration

mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

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

as stipulated and demanded by the aforementioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.
Oxygen Concentrator	12-873	DE/CA09/0760/044
Continuous Positive Airway Pressure Units	11-001	DE/CA09/0760/045

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

September 2010

Werner Sander
President & CEO