



EU DECLARATION OF CONFORMITY

INOGEN PORTABLE OXYGEN CONCENTRATORS

LEGAL MANUFACTURER	
Registered Trade Name	INOGEN, Inc
Address	859 Ward Drive, Suite 200 Goleta, California 93111 USA
SRN	US-MF-000027368
EUROPEAN AUTHORIZED REPRESENTATIVE	
Registered Trade Name	INOGEN Europe B.V
Address	Rijnzathe 7, 3454 PV De Meern, The Netherlands
SRN	NL-AR-000033111

INOGEN, INC states that this EU declaration of conformity is issued under its sole responsibility as manufacturer of portable oxygen concentrators (POCs).

PRODUCTS

The following products fall under Basic UDI-DI 081713102POCBU for Inogen POCs:

Ref Number	Product Name	UDI-DI	EMDN
IS-400	Inogen One® G4 Portable Oxygen Concentrator	00817131020179	Z12159004
IS-501	Inogen Rove 6™ Portable Oxygen Concentrator	00817131020513	Z12159004
IS-401	Inogen Rove 4™ Portable Oxygen Concentrator	00817131020414	Z12159004

Inogen POCs are configurable systems created from a combination of the following individual components, see table below.

Inogen POC system	IS-400	IS-501	IS-401
Component designation	Part Number	Part Number	Part Number
Portable Oxygen Concentrator	IO-400	IO-501	IO-401
Standard, Intermediate or Extended battery	BA-400 (Standard), or BA-408 (Extended)	BA-500 or BA-508 (Standard), or BA-516 (Extended)	BA-400 (Standard), BA-404 (Intermediate) or BA-408 (Extended)
AC Power Supply & Power cable (market-specific cable)	BA-401	BA-501 or BA-502	BA-402
DC Power Cord	BA-306	BA-306	BA-306
Carry Bag	CA-400 and CA-401 (Carry strap)	CA-500	CA-400

INTENDED PURPOSE

The Inogen POCs provide a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis.

RISK CLASSIFICATION

Portable Oxygen Concentrators are Class IIb medical devices, according to rule 12 of MDR Annex VIII.

INOGEN Inc, states that the **portable oxygen concentrators** covered by this declaration are in conformity with

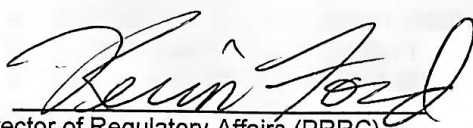
- Annex I of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC) (MDR)
- COUNCIL DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

CONFORMITY ASSESSMENT PROCEDURE:

The conformity of the Portable Oxygen Concentrators listed above has been assessed in accordance with the MDR annex IX Chapter I and Chapter III, by BSI The Netherlands (2797).

EU Quality Management System certificate reference: MDR 753560 R000.

Place: Goleta, CA USA

Signed: 
Title: Director of Regulatory Affairs (PRRC)
Kevin Ford

Date: 18 September 2024