



EC Declaration of Conformity

Invacare Corporation (Manufacturer)
2101 Lake Mary Blvd
Sanford, Florida 32773
USA

EC-Hong A/S (Distributor)
Ostergade 3
DK-4270 Hong
Denmark

Declares that the medical device described hereafter

Invacare Twilight II Nasal Mask

ISP2100SMAW, ISP2100STDAW, ISP2100LAW

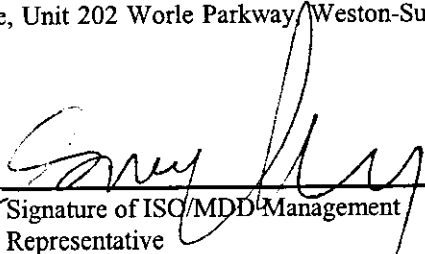
Classification of IIa using Annex IX, Rule 11, is in conformity with the essential requirements and provisions of Council Directive 93 / 42/ EEC and is in conformity with the following national standard(s)

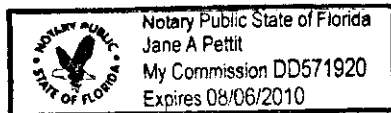
ISO 17510-2 :2003
ISO 5356-1 : 2004
ISO 10993
ISO 13485:2003

The Quality System for this product has been assessed according to the procedure of conformity assessment described in Article 11.2.b and Annex V coupled with Annex VII of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd, SGS House, Unit 202 Worle Parkway, Weston-Super-Mare, North Somerset, BS226WA, United Kingdom.

Invacare, Florida Operations

Place and date of issue


Signature of ISO/MDD Management
Representative



Jane A Pettit
3/01/2007

Name: Gerry Finley
Title: QUALITY MANAGER
On behalf of: INVACARE