



## EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC, as amended by the Council Directive 2007 concerning medical devices

We,

*COMFORT Orthopedic Co., Ltd.* (Manufacturer Name)

No. 120, Nan Shiang Tsuen, shoei Shang Shiang, Chia-Yi, Taiwan, ROC.

(Place, Manufacturer Address)

declare under our sole responsibility that the following non-sterile products under Class I meet the provisions of the Council Directive 93/42/EEC, as amended by the Council directive 2007/47/EC, concerning medical devices which apply to them:

For the following equipment:

**MANUAL WHEELCHAIR**

Model:  SL-7540  LY-7100C-AE  LY-7100C-FB  LY-5000  LY-5010  LY-5100  SL-9512  
 SL-9200  SL-9001  SL-9002  SL-9003  SL-8681  SL-8581  SL-8580  SL-7100C-AE  
 SL-7100A-FB-12  SL-7100A-12  SL-7100A-FB-24  SL-7100A-24  SL-5000  TR-5000  
 SL-4760  SL-3760SF-FB  SL-2850  S5-8A500SEF  S4-8A140SF  K1-1850  K1-1700  
 S2-8A750SF  S3-812A700SF  S9-8A750SF  S0-8A100FF  S0-8A100HF-FB  CH-8A100F  
 CH-5C100FF  LY-5C250SF  LY-8A200SF  LY-8A250SF  LY-8A100SF  CJ-8B250SEF-I  
 LY-812A250SF-NR  CR-808A100SF-FB-PB  LY-8C250SF  CE-808N100SF  CJ-8L750SF  
 CJ-8H750SF  CJ-8M750SF  S7-816A210SEF-FB  K6-2750  SL-4850

(Model Designation)

The products are intended to be used as the assistant device mainly used by the people inconvenient while walk people with disabled lower limbs, old people for helping their movement.

Conformity assessment was performed according to Article 11 (5), Annex VII Section 3. Of the Council Directive 93/42/EEC as amended by the Council Directive 2007/47/EC.

The following standards were used to prove the products conformity with the essential requirements of the above ISO 9001, ISO 13485, EN980:2008, EN 14971/2009, EN60601-1:1990, EN60601-1-2:1993

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a.

**Corporate Office:**

53 Bd. Général Wahis  
B-1030 Brussels, Belgium

Phone: 32.2.732.59.54

Fax: 32.2.732.60.03

E-mail:

Representative: Mr. Gideon ELKAYAM

**Registered address :**

Avenue de Tervuren, 34, box 44

B-1040 Brussels, Belgium

General Manager

(Position/Title)

(Legal Signature)

*Janson Chen*



Chia-Yi, Taiwan 2010/04/22

Issue place and date