

COMFORT ORTHOPEDIC CO., LTD.
120 NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI TAIWAN R.O.C.
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EC DECLARATION OF CONFORMITY

According to annex VII of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC, 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 :
K9-8A750SF, K9-8J750SF, K9-8F750SF, K9-812A750SF, K9-812F750SF, K9-812J750SF
K7-8A750SF

(Model Designation)

The products are intended to be used as the assistant device mainly used by the people inconvenient while walking including the 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 directive:

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, Bd. Général Wahis 53, 1030 Brussels, BELGIUM

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General Manager

(Position/Title)

(Legal Signature)

Chia-Yi, Taiwan, 17-Jun-2014

Issue place and date