

EU DECLARATION OF CONFORMITY

We, Comfort Orthopedic Co. Ltd., No. 120, Niouchoupu, Nan Shiang Tsuen, Shoei Shang Shiang, Chia-Yi, Taiwan, R.O.C., hereby declare under our own responsibility that the following products:

Please refer to the Annex to EU Declaration of Conformity

meet the provisions of the Medical Device Regulation 2017/745/EU as amended by 2020/561/EU and the essential requirements which apply to them.

The abovementioned devices have been classified as class I device according to rule 1 set out in Annex VIII of the Regulation 2017/745/EU.

This declaration is supported by the Quality Management System certification ISO 13485:2016/ASR Certificate No. 8148 issued on 25/11/2020 and delivered by AMERICAN SYSTEMS REGISTRAR, LLC., 5281 Clyde Park Ave. SW, Suite 1, Wyoming, MI 49509 USA.

This declaration is based on the conformity assessment of products to the requirements of Annexes II and III.

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer"

COMFORT ORTHOPEDIC CO., LTD.

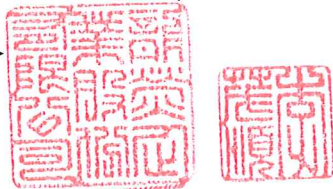
Chia-Yi, Taiwan, 30/ July /2021

alan lee

Issue place and date (DD/MM/YY)

<Manufacturer's Signature>

<Stamp>



<Name> Alan Lee

<Position> General Manager

European Authorized Representative:

Registered Address:
Y. Sung Handelsvertretung
Duesselthaler Str. 24
40211 Duesseldorf Germany

Annex to EU Declaration of Conformity

(Article 19, the Medical Device Regulation 2017/745/EU)

No.	MBK CODE	Model	GR DESCRIPTION	EN DESCRIPTION	Class**	Rule
1	0806240	LY-ESB240-42	ΑΝΑΠ.ΑΜΑΞ.ΗΛΕΚΤΡ.ΕΝ ΙΣΧΥΜΕΝΟ "ANGEL" (42εκ) (ΚΠ)	Power standing wheelchair "ANGEL" (42 cm)	I	1
2	0806242	LY-ESB140	ΟΡΘΟΣΤΑΤΗΣ "HERO 4" (46εκ)	Semi-electric standing wheelchair HERO 4 (46cm)		
3	0806243	LY-ESA130	ΟΡΘΟΣΤΑΤΗΣ "HERO 3- Κ" (38εκ)	Semi-electric standing wheelchair HERO 3-K (38cm)		
4	0806244	LY-ESB240-46	ΑΝΑΠ.ΑΜΑΞ.ΗΛΕΚΤΡ.ΕΝ ΙΣΧΥΜΕΝΟ "ANGEL" (46εκ)	Power standing wheelchair "ANGEL" (46 cm)		