Declaration of Conformity

Manufacturer: Foshan Ecarre Medical Equipment Co., Ltd.
Address: No. 01-02, 4th Floor of Chenhairui Factory, Donglian Development Zone, Danzao Town, Nanhai District, Foshan City, Guangdong, 528216, China

Product name: MANUAL WHEELCHAIR

Model(s): WR6701A, WR6702FA, WR6703A-12, WR6704FA, WR6705, WR6706, WR6711J, WR6712J, WR6713J, WR6714J, WR6715J, WR6715J, WR6730, WR6731ABJ, WR6732ABJ, WR6733ABJ, WR6734AJ, WR6735AJ, WR6868LJ, WR6864LJ, WR6736LAJ, WR6908LJ, WR6950LQ, WR6952LCQ, WR6903L, WR6903LQ, WR6863LABJ-20, WR6863LAJ-16, WR6806LB, WR6805LABJ, WR6874LJF5, WR6870LABJF5, WR6980LA-30, WR6890LA35, WR6980LA35, WR6980LF3-35, WR6980LQF8, WR6736, WR6737, WR6738, WR6739, WR6740, WR6790BGC, WR6958LBYG, WR6954LGC, WR6204FBJ, WR6258LBYGP, WR6954FGC, WR6903FGC, WR6971, WR6972, WR6973, WR6974, WR6909F, WR6909FB, WR6908FAQ, WR6901F, WR6901FB, WR6902FC, WR6903F, WR6904FB, WR6904FBJ, WR6972FB, WR6973FBC, WR6874F5, WR6874F, WR6809F, WR6802-35F, WR6809FB, WR6951FB-56, WR951FAC-56, WR6209FAE-61, WR6210FQ-60, WR6863FAJ, WR6760F, WR6761F, WR6762F, WR6763F, WR6764F, WR6765F, WR6608FGC, WR6609FGC, WR6609FGCJ, WR6954LGCU, WR6608F, WR6609F, WR6681F, WR6608FB, WR6533, WR6534,WR6502, WR6532, WR6503S, WR6504S, WR6505F, WR6500, WR6692F, WR6695F, WR6501S, WR6506, WR6507, WR6508, WR6635, WR6636, WR6737LQ-36, WR6734LQ-36, WR67311LQ-36, WR6730LQ-36, WR6732LQ-36, WR6727LQ-36, WR6720LQ-36, WR6723LQF1-36, WR6723LQ-36, WR6721LQ-36, WR6722LQ-36, WR6770LQ-32, WR6771LQ-32, WR6779LQ-36, WR6777LQ-36, WR6778LQ-36, WR6717L-30, WR6710L-30, WR6786LQ-36, WR6785LQ-36, WR6740LQ-36, WR6766LQ-36, WR6755LQ-36, WR6735LQ-36, WR6744LQ-43, WR6756LQ-36

Type: Class I, rule 1

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 62366-1:2015, ISO 10993-1:2018, ISO 10993-5:2016, ISO 10993-10:2010, ISO 7176-1:2014 and series

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.

European Authorized Representative
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CE

This declaration is issued under the sole responsibility of the manufacturer.

Karen Wei

Signature of Authorized Person
Karen Wei
Title: Compliance manager
Place: Foshan City

DOC №: D-YG-MD-220725013/05
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