## **EC Declaration of Conformity**

## Issued in accordance with EC Directive 93/42/EEC relating to Medical Devices

Guangdong Road Mate Group Co., Ltd.

Manuacturer: No. 16 Yongyi 6th Road, Henglan Town, Zhongshan

City, Guangdong Province, China

Product description & Item Number:

Major Elite Cardinal/Charcoal - NOX01011

Major Elite Soft Blue/Navy - NOX01021

Applied directives: Medical Device Directive 93/42/EEC

We declare, using the conformity assessment route, through Council Directive 93/42/EC of 14 June 1993, concerning Medical Devices, Annex VII, as amended by Directive 2007/47/EC, that

the listed products manufactured for sale by other distributors, classified using Annex IX, Rule 1 of Council Directive 93/42/EEC, as Classes I,

meet the essential health and safety requirements and are in conformity with the relevant EC directives listed below using the relevant sections of the following EC standards and other normative documents:

Council Directive 93/42/EC of 14 June 1993, Concerning Medical Devices, as amended by Directive 2007/47/EC

ISO-7176-1:2014 Wheelchairs - Part 1: Determination of Static Stability

ISO-7176-3:2012 Wheelchairs - Part 3: Determination of Efficiency of Brakes

ISO-7176-8:2015 Wheelchairs - Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths

Article 57 of No. 1907/2006 REACH Regulation, SVHC content

REACH Regulation (EC) No.1907/2006 Annex XVII, Item no. 43, Points 1 and 2 - Azo Dyes

REACH Regulation (EC) No.1907/2006 Annex XVII, Item no. 51 - Phthalates

REACH Regulation (EC) No.1907/2006 Annex XVII, Item no. 52 - Phthalates

REACH Regulation (EC) No.1907/2006 Annex XVII, Item no. 23 - Cadmium

Schedule 2 Part I of the Furniture and Furnishings (Fire) (Safety) Regulations 1988, BS 5852

EN71-3:2013+A3: 2018 Safety of toys - Part 3: Mirgration of certain elements

Signed for and on behalf of Guangdong Road Mate Group Co., Ltd.

Names: Zhong Jianhui

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**Position: QA Manager** 

Place of issue: China

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