

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC) including Directive 2007/47/EC

Manufacturer:

YONGKANG BEIQIN INDUSTRY AND TRADE CO.,LTD

Address:

132 XIABAISHI ROAD ZHIYING TOWN, YONGKANG, ZHEJIANG, CHINA

EC Representative:

SUNGO Europe B.V.

Address:

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name:

Safety Frame

Specification:

701A,702B,703C704D,705E,706F,707G,708H,801A,802B,803

ication.

C,804D

Classification:

Class I (MDD, Annex IX)

Conformity Assessment

Annex VII of Medical Device Directive(93/42/EEC)

Procedure:

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) including Directive 2007/47/EC and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

Signature DANGM

Namé/Position: ANGM

Date: 2000 1 16

Place: zhejiang/China

CE

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SUNGO Europe B.V.

Address:

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Product Name:

Commode Chair

Specification:

6001A,6002B,6003C,6004D,7001A,7002B,7003C,8001A,8002B

Classification:

Class I (MDD, Annex IX)

Conformity Assessment

Procedure:

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EN ISO 15223-1:2016

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Signature: Name/ Position

Date:

Place: Zhejiang



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EC Representative:

SUNGO Europe B.V.

Address:

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name:

Shower chair

Specification:

101A,103C,201A,202B,203C,204D,301A,302B,401A,402B,403

C,404D,501A,502B,503C,601A,603C,604D,605E

Classification:

Class I (MDD, Annex IX)

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Signature:

Name/ Position: 3

Date:

Place: Zhejiang China



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EC Representative:

SUNGO Europe B.V.

Address:

Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name:

Rollator

Specification:

1001A,1002B,1003C,1004D,1005E,2001A,2002B,3001A,3002B,30

03C,3004D,3005E,4001A,5001A,5002B,5003C,5004D,8003C

Classification:

Class I (MDD, Annex IX)

Conformity Assessment

Procedure:

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Place: Zhejiang