# Declaration of Conformity

Manufacturer: R. Poon Medical Products Co., Ltd.

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European Shanghai International Holding Corp. Gmbh (Europe)

Representative: Eiffestrasse 80, 20537 Hamburg Germany

Tel: 0049-40-2513174 Fax: 0049-40-255726

Product: Shower / bath bench, W or W/O back

## Classification (MDD, Annex IX):

According to requirements of COUNCIL DIRECTIVE 93/42/EEC ANNEX IX, rule 1, Shower Chairs are in class I as non-invasive and non-implantable medical devices. Thus COUNCIL DIRECTIVE 93/42/EEC ANNEX VII is chosen as conformity assessment procedure.

## We herewith declare that:

The above-mentioned products meet the provisions of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices and Standards. All the products can fulfill its intended use. All supporting documentations are retained under the premises of the manufacturer and the notified body.

## General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

### Applicable Standards:

MDD (93/42/EEC), IS013485: 2003, IS09001: 2000, IS0 14971: 2000, IS014155-1:2003, EN10993: 2003, EN12182: 1999 EN1985: 1999, EN980: 2003, EN 1041: 1998, EN IS011199: 2002

Notified Body: TÜV Product Service GmbH,

Certificate: ISO13549:2003

Date: 01-04-2006

Manufacturer: R. Poon Medical Products Co., Ltd.

Signature:

Position: Vice General Manager&Manager Representative