

DECLARATION OF CONFORMITY

Manufacturer: BAO-Health Medical Instrument Co., Ltd.
2ND Floor Of 8-2 Building, Gaoqiao Industrial Zone, Tongxiang,
Zhejiang Province, 314515 P.R. China

European Representative: **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich Germany
DIMDI Code: DE/0000047791

Product Name: **Ostomy bags**

Models: **Single-use Non-sterile Urostomy Bags, Single-use Non-sterile
Colostomy Bags, Single-use Non-sterile Ileostomy Bags**

Classification (MDD, Annex IX): **Class I / Rule 1**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Signature:

Name: Chengbin Zhang

Position: General Manager



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