

扬州卓合进出口有限公司

YANGZHOU SUPER UNION IMPORT AND EXPORT CO., LTD

ADD: NO.118 XISHAN SOUTH ROAD, CHENJI TOWN, YIZHENG CITY, JIANGSU PROVINCE, CHINA

Declaration of Conformity

Manufacturer: Yangzhou Super Union Import and Export CO., LTD.

NO. 118 Xishan south road, Chenji town, Yizheng City, Jiangsu Province China.

Product name: Cutting cotton roll

Size: 70g; 100g; 250g

Brand name: SUGAMA

Classification/Rule: MDD93/42/EC Class I Non sterile/Rule 1

Conformity Assessment Route: Annex VII

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.

DIRECITVES

General applicable directives

Medical Device Directive: MDD 2007/93/42/EC

Standard Applied:

ISO 13485:2003 ISO 14971:2007 ISO 11137-2006 ISO 11737:2006 ISO 11607:2006

EN 980:2008 EN 14073:2003 ISO 10993:2002 ISO 14155:2003 ISO 2856-1:1999

Signature: _____

Name: Shaohongfeng

Position: QA Manager

