



宁波海曙昊润医疗器械有限公司
NINGBO HAISHU HAORUN MEDICAL DRESSING CO.,LTD

NANZHAN ROAD NO.66 HAISHU NINGBO ZHEJIANG CHINA 315000
www.haorunmed.com sales@haorunmed.com TEL:+8657487706193

Manufacturer Declaration of Conformity
Regarding Medical Device Regulation(EU) 2017/745

Manufacturer:

Name :Ningbo Haishu Haorun Medical Dressing Co., Ltd.

Address: No. 66 Nanzhan Road (E) Haishu District, Ningbo, 315000, Zhejiang, People's Republic of China

Tel: 86-574-87706193 Fax: 86-574-87706193

mail: 1277073950@qq.com

SRN:CN-MF-000019050

European Representative

Name: ZOUSTECH S.L.

Address: Pso. Castellana, 141 – Planta 19, 28046 – Madrid, Spain

Tel: +34694426446 Fax: +34917915466

mail: legal@zoustech.eu

Product name:Pop Bandage,Non-sterile Gauze Swab,Non-sterile Gauze Roll,Non-sterile Gauze Bandage,Non-sterile Cotton Wool

Model/Size:all size

Classification (MDR, Annex VIII,rule 4): Class I

Conformity Assessment Procedure: Annex II+AnnexIII

We herewith declare under our sole responsibility that the above mentioned products meet the Medical Device Regulation(EU) 2017/745 and the following standards. All supporting documentations are retained under the premises of the manufacturer.

EN ISO 13485:2016	ISO 14971:2019	EN ISO 10993-1:2018
EN ISO 10993-5:2009	ISO 10993-10:2010	EN 14079:2003
EN 1041:2008	ISO 11737-1:2018	ISO 15223-1:2021

Signature of issue person: _____

Name: Gang Li

Position: General Manager

Place: Ningbo, China

宁波海曙昊润医疗器械有限公司
NINGBO HAISHU HAORUN MEDICAL DRESSING CO.,LTD