



NINGBO GREETMED MEDICAL INSTRUMENTS CO., LTD.

Declaration of Conformity

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.

Address: 16F-1, No.1 Building, Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, PEOPLE'S
REPUBLIC OF CHINA

Tel: 86-574-87739070 Fax: 86-574-87722360

European Representative:

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Tel:+49-40-2513175 Fax:+49-40-255726

Email: shholding@hotmail.com

Product Name: ECG Gel

Model: GT148-200

Size: 250ml

Technical Parameter: pH value: 5.5-7.3

Viscosity: (25°C): ≥15Pa.s

Velocity of sound: 1520-1620 m/s

Electric resistance: (35°C)-13-17

Acoustic impedance: 1.5-1.7x10⁶ Pa

Acoustic attenuation: ≤0.05dB/(cm.Mhz)

Classification (MDD, Annex IX): I

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.

DIRECTIVES

General applicable directives:

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

Standard Applied: All applicable harmonized Standard (publish in the Official Journal of the European Communities)

Signature:

Name: Li Guirong

Position: General Manager

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