

# EU Declaration of Conformity

**Manufacturer:**

Name: Taizhou Xinkang Medical Materials Co., Ltd.  
Add: No.18, Wuzhou(South) Road, 225300 Taizhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA  
Tel: +86(523)86848901 Fax: +86(523) 86848738  
SRN: CN-MF-000012941

**European Representative:**

Name: Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
SRN: DE-AR-000000001

**Product Name:** Emergency Blanket

**Model/Size:** 130cm x 210cm, 140cm x 210cm, 140cm x 220cm, 160cm x 210cm, 130cm x 185 cm, 230cm x 230cm, 100cm x 200cm, 92x132cm

**Intended Use:** It is used for keeping warm and preventing sunburn.

**Risk Class of the Device:** The medical device has been assigned to class I, rule 1 according to ANNEX VIII of MEDICAL DEVICE REGULATION (EU) 2017/745.

**The UMDNS code:** 10416

**Product Certification Conformity Assessment Route:** Annex II, Annex III of MEDICAL DEVICE REGULATION (EU) 2017/745.

**Basic UDI-DI:** 69531026EBF0506ANSN4

The medical device has been assigned to class I according to ANNEX VIII of MEDICAL DEVICE REGULATION (EU) 2017/745. It bears the mark **CE**

The medical device has been designed and manufactured under a quality management system according to ANNEX IX of MEDICAL DEVICE REGULATION (EU) 2017/745.

This Declaration of Conformity is valid in connection with the released document for the respective batch.

We herewith declare that the above-mentioned products meet the provisions of Medical Device REGULATION (EU) 2017/745. All technical documentations are retained under the promises of the manufacturer.

The above mention Declaration of Conformity is exclusively under the responsibility of Taizhou Xinkang Medical Materials Co., Ltd.

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**General Applicable Regulation:**

MEDICAL DEVICE REGULATION (EU) 2017/745

Taizhou, 2024-03-05

*Place, date*

Tang Yujun, General Manager

*Legally binding signature, Function*

