DANYANG RAPID AID HOT AND COLD THERAPY PRODUCTS CO., LTD

Glasses Industrial Park,Danfu Road,Danyang,Jiangsu,China 212300

Tel: +86 0511 88013009 Fax: +86 0511 88013001

Declaration of Conformity

Manufacturer:

Danyang Rapid Aid Hot And Cold Therapy Products Co., Ltd

Glasses Industrial Park, Danfu Road,
Danyang, Jiangsu, China 212300

Whose single Authorized Representative:

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

We, the manufacturer, herewith declare that the products

Instant cold pack

PN#: CPACKL,CPACKP,CPACKS.

meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to classification rule (rule 9) of Annex IX of the Directive 93/42/EEC. It bears the mark

CE **1639**

The product concerned has been manufactured under quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated products with the Directive 93/42/EEC has been assessed and certified by the Notified Body

Our products comply with the following standards：

EN ISO 15223-1-2016 Medical devices - used for medical equipment labels, tags and provide the information of symbols. General requirements

EN ISO 10993.1：2009 Biological evaluation of medical apparatus and instruments, part 1: evaluation and test in the process of risk management

EN ISO 10993.5：2009 The biological evaluation of medical devices in part 5: cytotoxicity test in vitro

EN ISO 10993.10：2013 Medical biological evaluation part 10: to stimulate and delayed-type hypersensitivity test

EN ISO 14971:2012 Medical devices - application of risk management

EN ISO 13485:2012 Medical equipment- quality management system requirements

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EN 1041:2008 Information supplied by the manufacturer of medical devices

EN 62366:2008 Medical devices. Application of usability engineering to medical devices

EN 980:2016 Symbols for use in the labelling of medical devices

SGS Belgium NV Systems & Services Certification
House Noorderlaan 87 2030 Antwerp Belgium
Tel: +32 (0) 3 545-48-48 Fax: +32(0)3 545-48-49
Certificate No.: SGS CN19/41045

Issue date: 16 Dec 2019

Expiry date: 24 May 2024

following the procedures relating to the Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release documents for the respective batches of produced devices.

The above mentioned declaration of conformity is under the responsibility of

Company: **Danyang Rapid Aid Hot & Cold Therapy Products Co., Ltd**

Address: **Glasses Industrial Park,Danfu Road,Danyang,Jiangsu,China 212300**

Danyang Jiangsu China, 2020.02.08 Lingo Wang/Quality Manager

Place , date Legally binding signature, Function