EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60125291 0001

Report No.: 16806993 001

Manufacturer:
Koolcare Technology Co., Ltd.
No.6-10, A5, Shandong International
Tech Park
South Waihuan Road
Linyi
276017 Shandong
China

Products:
- Instant Hot Packs
- Hot Packs/Heat Pads
- Instant Cold Packs
- Heat Wraps

Expiry Date: 2023-01-10

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-03-19

Date: 2018-03-19

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.