



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 12 02927 002

Manufacturer: **Yancheng Kellyunion Import and Export Co., Ltd.**

Building 2, No. 17 Yandu East Road, Xinhe Street
Chengnan District

224005 Yancheng, Jiangsu

PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Prolinx GmbH**

Brehmstr. 56

40239 Duesseldorf

GERMANY

Product Category(ies): **Digital Thermometers,
Blood Pressure Monitor,
Infrared Forehead Thermometer**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH17127001

Valid from: 2018-05-08

Valid until: 2023-05-07



Date, 2018-05-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate**Production Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 12 02927 002**Facility(ies):**

Yancheng Kellyunion Import and Export Co., Ltd.
Building 2, No. 17 Yandu East Road, Xinhe Street,
Chengnan District, 224005 Yancheng, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA