



Product Service

# CERTIFICATE

No. Q1N 17 03 76635 003

**Holder of Certificate:** Xinjiang Ke Lan Shuang Yi Medical Technology Stock Co., Ltd.  
 No.285 Donghuan Road  
 Tianshan District  
 830002 Urumqi, Xinjiang  
 PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Xinjiang Ke Lan Shuang Yi Medical Technology Stock Co., Ltd.  
 No.285 Donghuan Road, Tianshan District,  
 830002 Urumqi, Xinjiang, PEOPLE'S REPUBLIC OF CHINA



**Certification Mark:**



**Scope of Certificate:** Design, Development, Production and Distribution of Thermoplastic Fixation Mask for Radiotherapy, Thermoplastic Orthosis and Low Temperature Thermoplastic Material.

**Applied Standard(s):** EN ISO 13485:2012 + AC:2012  
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
 DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** BJ1776104

**Valid from:** 2017-06-16

**Valid until:** 2020-06-15

*S. Preiß*

**Date,** 2017-05-31

Stefan Preiß



Page 1 of 1

