

# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 2067019-1

Organization: Quality Synthetic Rubber (Dongguan) Inc.  
(QURE MEDICAL Division)  
No. 1 Building E Section, Junda Industry Zone,  
Dongkeng District, Dongguan,  
523457 Guangdong  
P.R. China

Scope: Contract Manufacture of silicone parts for medical use

  
**TÜVRheinland**<sup>®</sup>

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10920285-100  
Effective date: 2022-04-18  
Expiry date: 2025-03-09  
Issue date: 2022-04-18



Fuxiu Sheng  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Quality Synthetic Rubber (Dongguan) Inc. (QURE MEDICAL Division) No. 1 Building E Section, Junda Industry Zone, Dongkeng District, Dongguan, 523457 Guangdong P.R. China	License holder only
/02	c/o Quality Synthetic Rubber (Dongguan) Co., Ltd. DongKeng Branch Room 101, Building 1, No.10, 2nd Road, Dongxingyuan, Dongkeng District, Dongguan, 523452 Guangdong P.R. China	Contract Manufacture of silicone parts for medical use

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