

# Certificate



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

Registration No.: SX 2057242-1

Organization: Elkem Silicones Shanghai Co., Ltd.  
No. 3966 Jindu Road, Xinzhuang Industrial Zone,  
201108 Shanghai  
P.R. China

Scope: Design, Development, Manufacture and Distribution of Silicone Material for  
Medical Devices

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.

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