

Certificate SG13/04368

The management system of

# D&K ENGINEERING PTE. LTD.; D&K Engineering Services Sdn. Bhd.

No. 2 Corporation Road, #02-07/12, Singapore 618494

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

D&K ENGINEERING PTE. LTD.:

Contract Manufacturing of Electro-Mechanical Assemblies for Active Medical Devices (Non-implantable)  
Design and Development of ENT Tympanostomy surgical device with software

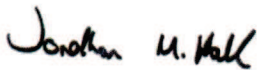
D&K Engineering Services Sdn. Bhd.:

Contract Manufacturing of Electro-Mechanical Assemblies for Active Medical Devices (Non-implantable)

This certificate is valid from 29 March 2024 until 24 April 2025 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 25 April 2013

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

Jonathan Hall  
Global Head - Certification  
Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - [www.sgs.com](http://www.sgs.com)



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Certificate SG13/04368, continued

# D&K ENGINEERING PTE. LTD.; D&K Engineering Services Sdn. Bhd.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 7

## Sites

D&K ENGINEERING PTE. LTD.

No. 2 Corporation Road, #02-07/12, Singapore 618494

Contract Manufacturing of Electro-Mechanical Assemblies for Active Medical Devices (Non-implantable)  
Design and Development of ENT Tympanostomy surgical device with software

D&K Engineering Services Sdn. Bhd.

No. 8 Jalan Indah Gemilang 6, Taman Perindustrian Gemilang, 81800 Ulu Tiram, Johor, Malaysia

Contract Manufacturing of Electro-Mechanical Assemblies for Active Medical Devices (Non-implantable)



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