



Certificate AU12/4100.00

The management system of

# I D & E Pty Ltd

701-703 Parramatta Rd, Leichhardt, NSW 2040  
Australia

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 03 August 2021 until 02 August 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 8. Certified since 03 August 2012

This is a multi-site certification. Additional site details are listed on the subsequent page.

Authorised by



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SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
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21HC-13485-2016-0421-M2

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**I D & E Pty Ltd**

**ISO 13485:2016  
EN ISO 13485:2016**



Issue 8

Detailed scope

**701-703 Parramatta Rd, Leichhardt, NSW 2040 Australia:**

**Design and development of non-active medical devices, active medical devices (non-implantable), active implantable medical devices and in vitro diagnostic medical devices.**

**Contract Manufacturing and assembly of electro-mechanical components and sub-assemblies for use in non-active medical devices, active medical devices (non-implantable) and in vitro diagnostic medical devices.**

**Contract Manufacturing, assembly, warehousing, distribution and servicing of finished products which are either non-active medical devices, active medical devices (non-implantable) or in vitro diagnostic medical devices.**

Additional facilities

**Stationsplein 45, 3013 AK Rotterdam, Netherlands:**

**Design and development of non-active medical devices, active medical devices (non-implantable), active implantable medical devices and in vitro diagnostic medical devices.**



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Certificate AU12/4100.01

The management system of

# I D & E Pty Ltd

701-703 Parramatta Rd, Leichhardt, NSW 2040  
Australia

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design and development of non-active medical devices, active medical devices (non-implantable), active implantable medical devices and in vitro diagnostic medical devices.**

**Contract Manufacturing and assembly of electro-mechanical components and sub-assemblies for use in non-active medical devices, active medical devices (non-implantable) and in vitro diagnostic medical devices.**

**Contract Manufacturing, assembly, warehousing, distribution and servicing of finished products which are either non-active medical devices, active medical devices (non-implantable) or in vitro diagnostic medical devices.**

This certificate is valid from 03 August 2021 until 02 August 2024 and remains valid subject to satisfactory surveillance audits.

Recertification audit due a minimum of 60 days before the expiration date Issue 1. Certified since 03 August 2012

Multiple certificates have been issued for this scope

The main certificate is numbered AU12/4100.00

The validity of this certificate depends on the validity of the main certificate.

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21HC 13485 2016 0421

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Certificate AU12/4100.02

The management system of

# I D & E Pty Ltd

Stationsplein 45, 3013 AK Rotterdam, Netherlands

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design and development of non-active medical devices, active medical devices (non-implantable), active implantable medical devices and in vitro diagnostic medical devices.**

This certificate is valid from 03 August 2021 until 02 August 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 1. Certified since 03 August 2012

Multiple certificates have been issued for this scope  
The main certificate is numbered AU12/4100.00

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