Certificate AU12/4100.00

The management system of

ID & 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



SGS United Kingdom Ltd Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421 M2

Page 1 of 2





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Certificate AU12/4100.00, continued

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ID & 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

ID & 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

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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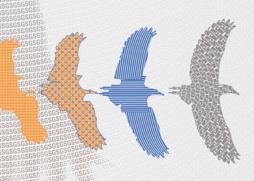








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Certificate AU12/4100.02

The management system of

ID & EPty 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

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

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