MONTROSE PTE LTD

Montrose R+ Pte Ltd

Your partner for development, regulatory and market access.

Introduction to Montrose R+ Pte Ltd

Montrose R+ Pte Ltd is specialised in development, regulatory and market access. Founded in 2017, we have helped many clients progress their product developments, by providing scientific and regulatory advice, through to gaining regulatory approval and marketing authorisation both nationally and internationally.

By gaining an understanding of clients' commercial needs, the key decision makers and route to market, we are able to recommend development, regulatory and market access solutions which help them achieve their milestones or bring their products efficiently to market, thereby maximising value from their asset.

regulanet® The Network

Montrose R+ Pte Ltd is a Joint Venture of **regulanet**® which is a global network of qualified independent consultancies with expertise in development, regulatory, market access, and lifecycle management throughout over 90 countries around the world.

Founded in 2001 by regenold GmbH, regulanet® consists of over 120 individual and partner organisations providing expertise in specific topics to a wide variety of national and international healthcare and pharmaceutical clients.

All cooperation partners are subject to a selection and qualification process and are reviewed on a continuous basis.

Pharma Services

- Strategic Advice
- Pharmaceutical Development
- Preclinical Development
- Clinical Development
- Project Management
- Regulatory Strategy & Implementation
- Pharmacovigilance
- Data Science & Analytics
- Auditing
- Market Access
- Portfolio Analysis
- Due Diligence
- Quality Management & Compliance

We offer customised solutions with a focus on innovative development plans in view of market access

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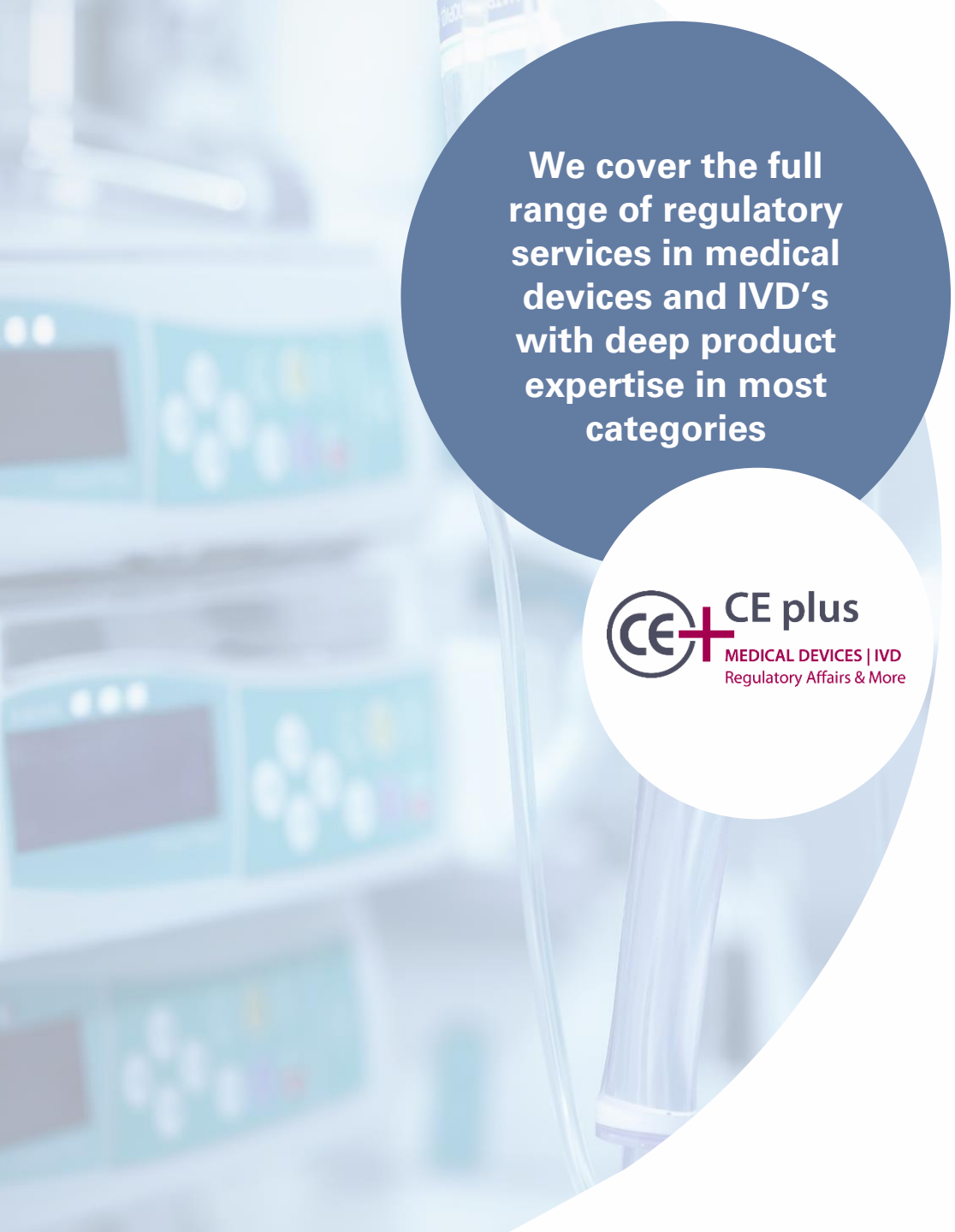

We cover the full range of regulatory services in medical devices and IVD's with deep product expertise in most categories

CE plus
MEDICAL DEVICES | IVD
Regulatory Affairs & More

MONTROSE PTE LTD

Medical Device & IVD Services

Technical Documentation
- Compilation
- Maintenance

Assessments
- Gap Assessments
- Due Diligence
- Clinical
- Biocompatibility

Quality Management System
- Implementation
- Maintenance
- Auditing

Market Access
- International Registrations in collaboration with regulanet®

Regulatory Strategies
- Design & Development
- Classification, CE marking

Post-Market Services
- Post-Market Surveillance
- Device Vigilance
- Regulatory Intelligence

Service portfolio of NEXTEC

- NEXTEC is a subsidiary of regenold GmbH and provides regulatory affairs services and takes over legal responsibility for medical devices and in-vitro diagnostics (MDR 2017/745 and IVDR 2017/746)
- “Legal” manufacturer service (MDR/IVDR Article 10)
- EU REP services (MDR/IVDR Article/11)
- Contract development for Medical device Software and Combination products (MDR/IVDR and EN ISO 13485:2016)

Product Expertise

- Medicines (Rx &OTC)
- Biopharmaceuticals
- Orphan Drugs
- Vaccines
- Medical Devices (including active, Software/Apps, and non active)
- In Vitro Diagnostics
- Combination Products
- Companion Diagnostics
- Borderline Products
- Herbal & Traditional Herbal Medicines
- Foods, including Novel food Applications
- Cosmetics
- Chemicals

Our Key Differentiators

Experience

Throughout the years we have helped over **2000 clients** with more than **10'000 products** and implemented **+100 QM Systems.**

Expertise

Our Subject Matter Experts possess **extensive practical experience** with backgrounds from industry as well as regulatory bodies.

Communi-cation

We offer **short response times** & dedicated contact points and we maintain **close communication** with Authorities and notified bodies.

Flexible Roles

Flexible roles such as Consultancy, Advisory Board, Regulatory Affairs Manager, Quality Manager, Project Manager etc..

State-of-the-art

Proven experience with **breakthrough technologies** including the use of AI / Digital Biomarkers.

Active member of **numerous networks**, working groups and standard committees.

One-Stop Shop

We provide tailored solutions for **all phases of the product life-cycle** including acting as Legal Manufacturer as well as European Representative.

MONTROSE PTE LTD

client benefits

We are passionate about regulatory – that is the reason why we provide a full range of development, regulatory and market access services

Ability to solve complex combination issues by coverage of both pharma and medical devices

Customised solutions tailored to individual client needs

Long-standing relationships with regulatory bodies

Leveraged by a proprietary network of regional and domain experts (regulanet®)

Project management focused on beginning-to-end responsibility to ensure client satisfaction

Regulatory responsibility services e.g. in PV, QM, legal representation

We provide expertise, people, and infrastructure (e.g. data science, validated, latest technology)

A private company with clients' interests at heart

Thank you.

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