



Our Mission

To exceed our customers' expectations in Quality, Service and Value.

Our Vision

To be the preferred and most trusted healthcare manufacturer for products that enhance patient care. Understanding the importance of the individual requirements of the institutions that we work with, Working Global, Acting Local.



6 international sites supporting in-market activities



25 years' experience in manufacturing



14% CGR High organic growth in last 3 years

Investing in the future

Flexicare was first established in November 1989 to acquire Aquaflex Medical (from Bespack, now Consort Medical), a contract manufacturing business whose core source of revenue was producing medical devices for blue chip healthcare companies.

It was evident from the outset that for the business to grow it would need to employ a new strategic direction and diversify into own branded production. With its expertise and experience in medical device manufacturing, Flexicare began its first advance into sales and marketing within the UK market under its own brand, during which time an opportunity arose to acquire the Venticaire and Ventimask range from Vickers PLC (a division of Vickers PLC now known as BAE Systems Land & Armaments).

With a dedicated sales force, revenues increased for the respiratory range which was bolstered by a growing product portfolio including respiratory, anaesthesia and continence care products. Flexicare is now one of the key suppliers to the National Health Service Supply Chain in the UK and also holds national contracts in Wales and Scotland.

To support the growth, Flexicare has invested in two state of the art manufacturing facilities and established subsidiaries in the USA, India and Australia as well as a Sales office responsible for the Middle East and Africa regions.

Being an independent and privately owned company, Flexicare's status allows selective product design, manufacture and distribution. From its roots in contract manufacturing, Flexicare has built a world class reputation, and continues its plans for expansion, providing local knowledge and support for its customers.

Milestones

1989	Flexicare Established & Acquired Aquaflex
1993	Acquired Venticaire Oxygen Therapy from Vickers Medical
1996	Relocated Headquarters to South Wales
2003	China Production Facility Opened
2007	Flexicare MEA Regional Office Opened
2007	Flexicare USA Subsidiary Opened
2009	Flexicare India Subsidiary Opened
2011	Acquired Firefly Medical, Rebranded to Calon Medical
2013	Flexicare Australia Subsidiary Opened
2014	Expanded HQ Office & Warehousing
2015	Manufacturing Facility in China To Be Expanded



Foreword

This Company Overview contains information relating to Flexicare Medical Limited and its product portfolio. The content of this document has been assembled based on input from distributors, agents and customers, and is intended to cover all of your requirements and those of your customers.

This document is intended to provide the reader with an overall understanding of Flexicare Medical Limited and, more specifically, of matters such as compliance with directives, regulations and standards. This document is designed to assist you when dealing with your end customers and / or your local regulatory authorities.

Confidentiality

The information contained in this Company Overview is the property of Flexicare Medical Limited and is disclosed in confidence to its distributors, agents and customers. This information should not, in whole or in part, be released to any third party without the prior written consent of Flexicare Medical Limited.

Document Control

This Company Overview is a controlled document. This document may be updated without notice. The current version is available from Flexicare Medical Limited upon request.

Accreditation

Flexicare is approved as a medical device manufacturer, meeting the requirements of the Quality Systems Standards ISO 13485 and ISO 9001 and the European Council Directive 93/42/EEC.

Flexicare is a registered establishment with the US Food and Drug Administration, Health Canada, and Japan's Pharmaceuticals Medical Devices Agency, amongst others.

Quality Policy

Flexicare is committed to delivering safe and effective, high quality products that meet the demands of clinicians in delivering optimal patient care. Through a comprehensive understanding of developing technologies, changing medical practice and the regulatory environment, Flexicare offers innovative solutions based on a foundation of Total Quality, Total Care.

Distributorships

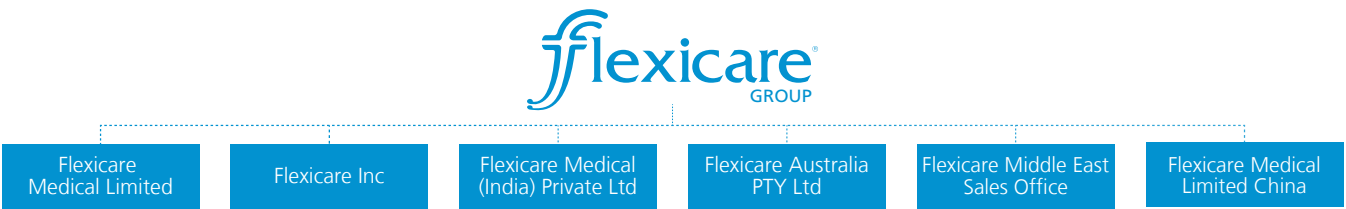
Although Flexicare currently exports to over one hundred countries, new and emerging markets are being scoped. If you are interested in becoming a distributor for Flexicare, please contact us for further information on enquires@flexicare.com

Content Accuracy Statement

Information is correct at time of release. Information is subject to change.



Company Structure



International Distributors

Flexicare now distributes to over 100 countries worldwide through a network of distributors and its own subsidiaries.

With a reputation for quality, service and value, Flexicare has developed many long standing partnerships internationally, with both local and globally established healthcare companies that are able to provide the same standards of customer commitment and care for which Flexicare is recognised.

Flexicare has offices across the UK, the Middle East, India, the Far East, Australia and the USA which are able to respond directly to customers' needs, providing a fast and efficient service. Working Global, Acting Local.

Investing for the future

Flexicare has invested and reinvested throughout its 25 years of research, design and manufacturing. Flexicare operates from two manufacturing facilities with a total of 246,000 sq ft of manufacturing and production, with the ability to support business expansion.

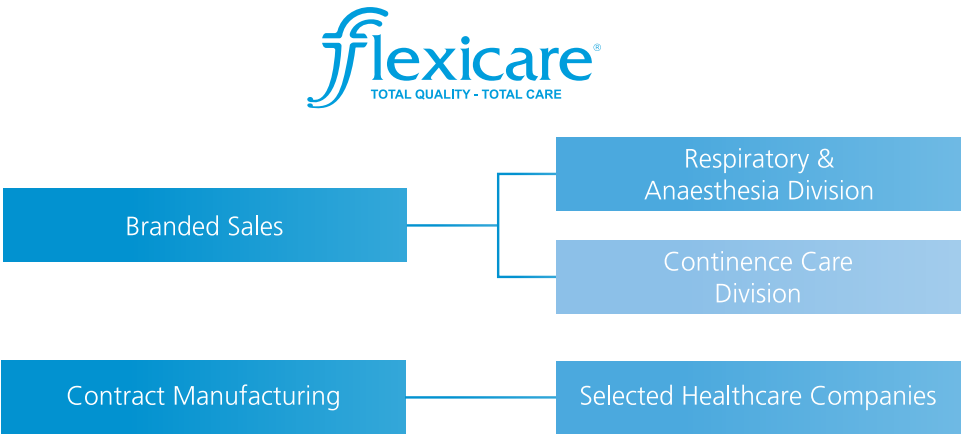
Flexicare operates a quality management system which is assessed and certified to ISO 9001, ISO 13485 and the European Medical Devices Directive 93/42/EEC. In addition Flexicare is also registered with the USA Food and Drug Administration (FDA).

Flexicare has also been registered in many countries around the world where there is a specific requirement such as Japan, Russia, South Korea, Australia amongst others.

Flexicare has taken a long term view to the growth of the business and has undertakings to expand its production capabilities at its current sites and other strategic markets in 2015/2016.

Business Divisions

Within Flexicare there are two distinct business divisions providing customised solutions to the healthcare industry as well as supplying the market directly under the Flexicare brand. With a strong focus on developing the Flexicare portfolio, the branded sales division accounted for 95% of all sales in 2014.





Product Divisions / Product Groups

Flexicare operates two distinct business divisions. The contract division provides customised solutions to the healthcare industry, while the branded sales division supplies the market directly with Flexicare products. The branded sales division is composed of two sub-divisions: Respiratory/Anaesthesia and Continence Care.

Company Registration / Incorporation

Flexicare Medical Limited is a registered ('incorporated') company in the United Kingdom and has been registered with Companies House under the Companies Act 2006.

Companies House is an Executive Agency of The Department for Business, Innovation and Skills.

Companies House holds the following information on Flexicare Medical Limited:

Company Number: 02428573

Status: Active

Date of Incorporation: 03/10/1989

Country of Origin: United Kingdom

Company Type: Private Limited Company

Nature of Business (SIC): 32500 - Manufacture of medical and dental instruments and supplies

FDA Establishment Registrations

Companies that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration and details of Flexicare's registrations are as follows:

- Flexicare Medical Limited, UK - 8021995
- Flexicare Medical (Dongguan) Limited, China - 3006061749
- Flexicare Inc, USA - 3005919257

Company Membership of Trade Associations

Flexicare Medical Limited is a member of Barema, the Association for Anaesthetic and Respiratory Device Suppliers, which represents over 70% of companies that manufacture or supply anaesthetic and respiratory equipment in or to the UK, working with the medical profession and other stakeholders.

Membership ensures Flexicare is a part of a continually developing sector and enhances patient safety and innovation between suppliers for the benefit of the patient.

For more information on Barema, please visit:
www.barema.org.uk

Medical Industry Accredited (MIA)

Flexicare ensures that all of our UK based sales and marketing personnel are MIA trained and accredited, which gives clinicians additional confidence in our staff when entering all areas of the hospital.

For more information on MIA, please visit:
www.miaweb.co.uk

Training & Support

Flexicare is dedicated to supporting Hospitals in training medical staff in the underlying principles associated with the product range that Flexicare provides.

This training can be accomplished by:

- a. "Train the Trainer" whereby a nominated Hospital staff member is chosen to undergo the training at Flexicare HQ and is then able to present the information to colleagues as necessary.
- b. Onsite training can be scheduled whereby a Flexicare representative or team of representatives will provide ward level training on Flexicare Products.
- c. Flexicare can also offer smaller groups the opportunity to visit the UK manufacturing facility to view how some of the products are manufactured, and the processes involved. Generally this is available on Tuesdays, Wednesdays and Thursdays. The group can then undergo training on the products that they are using which will also include presentations from our Quality Assurance and Customer Services team.



Investing in excellence

With a history of innovation and collaboration with University Hospitals and internationally recognised companies, Flexicare has always been dedicated to ensuring that all product developments envelope advances in product design that is centred around clinicians' and users' requirements. With the focus on innovation, Flexicare has launched several key products annually which have proven to be successful and these will be followed by a campaign of launches of new products in 2016 and further plans for the next 3 years.

Bill Mapleson Centre

Centre for clinical innovation, opened May 2014

The Bill Mapleson Centre, as a centre for clinical innovation, cements and develops already existing links between Cardiff University and the healthcare industry in Wales, the United Kingdom and internationally.

Professor Bill Mapleson started work in Cardiff in 1952, after gaining a BSc in Physics and completing his PhD on atmospheric electricity. He is best known for his paper in the *British Journal of Anaesthesia* in 1954, where he classified breathing systems, but his most significant achievements are related to pharmacokinetics and ventilators. Bill 'retired' in 1991, but still makes significant contributions to the development of research ideas and data analysis.

At this Cardiff University satellite site, The Bill Mapleson Centre will provide:

[Cutting-edge Focus Space for Innovation](#) working with industry for the good of patients.

[State of the Art Laboratory Facilities](#) for equipment development and testing: we have an internationally unique physics laboratory.



[Medical Training Space](#) for undergraduate and postgraduate students. The Bill Mapleson Centre offers students from many backgrounds the opportunity to develop and refresh their skills using state of the art simulators in a clinical environment.

Importantly, the space will provide cutting edge education for General Practitioners and Dentists with the facility to take the simulators into community practices. The space for this development in Mountain Ash, a Welsh Convergence area, has been provided in a ground-breaking agreement with Flexicare.



Product Development

Flexicare Medical Limited is strongly committed to working with leading Universities, Teaching Hospitals and Clinicians to develop ground breaking products that advance the delivery of patient care and improve patient safety. Through an understanding of the needs of healthcare providers, their patients, the challenges they face, and changing demands of delivering care, Flexicare's innovative partnership approach delivers solutions that make a real difference.

The experienced in-house Research & Development team, supported by skilled Engineers and Designers using the latest product development and manufacturing techniques, guide projects from concept through to clinical use. Even then the development does not stop, with post market surveillance and customer experience feeding back into continual product improvement and refinement.

Flexicare's modern manufacturing facilities enable close control of all parts of the development process, from rigorous testing of materials and rapid prototyping, through to the latest production processes that deliver high quality, innovative medical devices for clinicians to use.

Marketing Support Services

Flexicare's Marketing Team is based at the UK headquarters and produces a full range of media, including print, video and web. In addition, Flexicare attends the major international and national exhibitions relevant to the company's product range and supports local events through the design of banners and display materials.

Product Brochures, Flyers and Data Sheets are available for key strategic ranges and to support product launches. These can be produced in a range of languages as required.

Regularly updated brand guidelines are published for distributors, profiling the support materials, product brochures, flyers and other promotional items available from Flexicare.





AIRWAY MANAGEMENT

Range of airway management devices including Laryngeal Mask Airways, ET Tubes, Laryngoscopes, Guedel Airways and Nasopharyngeal Airways.



ANAESTHESIA BREATHING SYSTEMS

Standard Parallel, Bain, Paediatric and Custom Circuits. Ventiflow™ is a complete system for low flow anaesthesia, with options for monitoring line and APL valve.



ANAESTHESIA COMPONENTS

A wide range of components are available for clinicians to customise their circuits. Catheter Mounts, Connectors, Corrugated and Smoothbore Tubing and Water Traps.



VENTILATOR BREATHING SYSTEMS

Full range of invasive and non-invasive ventilator systems. Active humidification range including FL9000 Humidifier, heated-wire breathing systems and accessories.



NEONATAL BREATHING SYSTEMS

Range of Neonatal ITU Breathing Systems, Nasal Cannula, Anaesthetic accessories, ET Tubes, Laryngoscopes and Resuscitators suitable for neonatal care.



BREATHING FILTERS

Adult and Mini Electrostatic Breathing Filters and HMEF's. Adult and Paediatric Pleated Hydrophobic Bacterial / Viral Filters.



OXYGEN & AEROSOL THERAPY

Products include Fixed and Variable Concentration Oxygen Masks, Post Operative Oxygen Therapy, Nebulisers and Nebuliser Kits.



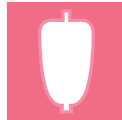
RESUSCITATION

Reusable and Single Patient Resuscitation Bags, Reusable Silicone Resuscitation Bags for Adults, Paediatrics and Neonatals.



SUCTION

The Flexicare range of Sterile Suction Tubing is made of PVC with Peel Pouch Sterile Packaging for easy opening and placing in sterile areas.



UROLOGY & CONTINENCE CARE

Complete link system for Hospital and Homecare including; Silicone Foley Catheters, leg-bags, drainage-bags and Urine measuring systems.



OSTOMY CARE

Flexicare offers closed and drainable bags; both are available in either one or two piece, with a choice of skin friendly backing.



ENEMA TIPS

Range of tips, bags and accessories providing clinicians with maximum choice. Wide range of enema tips with a choice of cuffed or uncuffed.

Registered

AeroCath®

BritePro®

LarySeal®

NasoSafe®

Venticaire®

Coloset®

BriteBlade®

MaxiNeb®

Ventimask®

Trade Mark

BritePro™ Solo

Dual Cannula™

Dual Mask™

NasoClear™

Ventiflow™

VentiShield™

CapnoCare™

Dual Guard™

IntegraBlade™

ThermoShield™

VentiSeal™

VentiSorb™



Legal Manufacturer

Flexicare Medical Limited
Cynon Valley Business Park
Mountain Ash
CF45 4ER
United Kingdom

Contract Manufacturer

Flexicare Medical (Dongguan) Limited
No.B-15, District, Xicheng Industrial Zone
Hengli Town, Dongguan City
Guangdong Province
China 523460

Commercial Relationship

Flexicare Medical Limited is the Legal Manufacturer.

Flexicare Medical (Dongguan) Limited is the Contract Manufacturer to Flexicare Medical Limited.

Flexicare Medical Limited as the Legal Manufacturer is responsible for the design, manufacture, sterilisation, packaging and labelling of medical devices before they are placed on the European and worldwide markets under the Flexicare brand.

Flexicare Medical (Dongguan) Limited, as the Contract Manufacturer, is responsible for the manufacture, sterilisation, packaging and labelling of medical devices to specifications agreed with and / or laid down by Flexicare Medical Limited.

Notified Body and Notified Body Number

SGS United Kingdom Limited
Unit 202b
Worle Parkway
Weston-Super-Mare
North Somerset
BS22 6WA
United Kingdom

Notified Body Number: 0120

Company Certification to ISO 9001 & ISO 13485

Flexicare Medical Limited has been approved as a medical device manufacturer by SGS in meeting the requirements of the Quality Systems Standards ISO 9001 and ISO 13485.

Company Certification to European Council Directive 93/42/EEC

Flexicare Medical Limited has been approved as a medical device manufacturer by SGS in meeting the requirements of the Council Directive 93/42/EEC concerning medical devices.

Manufacturing Facilities

Flexicare Medical Limited has purpose built facilities in the UK that cover 3500m², incorporating administration, manufacturing, assembly and warehousing. Flexicare's Class 100,000 (ISO Class 8) Cleanroom occupies 800m².

Flexicare Medical (Dongguan) Limited has purpose built facilities in China that cover 16434m², incorporating administration, manufacturing, assembly and warehousing. Flexicare's Class 100,000 (ISO Class 8) Cleanroom occupies 2356 m².

These facilities have been designed and built for the manufacture and packaging of Class I, IIa and IIb medical devices.

Contract Manufacturing

Flexicare Medical Limited offers best-in-class contract manufacturing services providing a complete solution to medical device companies.

Flexicare's expertise is founded on injection moulding, extrusion, welding, tool making and material development and selection. Flexicare's comprehensive contract manufacturing services include material planning and procurement, inspection, production, assembly, packaging and shipment.

By involving Flexicare at an early design stage, its knowledge and experience can be utilized to help achieve cost effective, high quality components and finished products.

Customisation Policy

Flexicare Medical Limited benefits from comprehensive in-house manufacturing facilities and an extensive product range that serves the needs of our customers in over 100 countries worldwide. Flexicare seeks to fully understand and satisfy the requirements of the global marketplace and is proud to offer a degree of customisation across many of its product ranges. If you have specific product customisation requirements, please contact your local Flexicare representative to discuss. Each project is subject to assessment on an individual basis for commercial and technical viability.

Commercial Information

Flexicare's Customer Services Team is available to respond to your enquiries, provide information regarding Flexicare's product range and discuss your requirements.



Flexicare (Group) Limited

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