POLIBRIXIA

BIOMEDICAL ENGINEERING

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Polibrixia is an engineering enterprise founded in 2005. It operates in the **mechanical, electronic and computer engineering** industry, in sectors ranging from automotive to food. After years of experience in the industry, **in 2020 Polibrixia** decided to **open its MEDICAL DEVICES Division** and dedicate expertise, space and investment to this new adventure.

> Creativity and superior excellence of research placed at the service of medical devices: feasible solutions within the timing dictated by the market.

Polibrixia has been an **INNOVATIVE SME since 2015** thanks to its strong belief in investing in R&D and proprietary patents.

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THE BIOMEDICAL PROJECT

We operate in the medical field as a facilitator of technological innovations.
We take charge of the entire product life cycle, from conception to manufacturing, implementing the functions and design of the device in relation to regulatory requirements.

We provide an innovative service featuring integrated manufacturing process management, with a holistic approach and maximum attention to detail to achieve the best possible user experience.

Complete design management of the medical device, **from conception to laboratory testing through to manufacturing.**

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MAIN SERVICES PROVIDED

- **Mechanical design:** from conception, to feasibility through to product definition and project execution.
- **Electronic design:** development of electronic aspects, test support, design and pre-series
- **Development** of standalone and embedded **software** (firmware)
- **Consulting** services during the preparation of documents
- **CE marking support** according to MDR (Medical device Regulation) Regulation (EC) 2017/745
- **Prototyping, industrialisation, and manufacturing.**

MAIN SECTORS OF EXPERIENCE

- **Non-invasive cardiovascular:** ECG, Holter, stress testing, multi-measurement monitoring, doppler systems, etc.
- **VAD** (Ventricular Assisted Device)
- **Blood glucose monitoring**
- Wide range of **software applications** in the welfare and healthcare sector
- Machines for **orthopaedic (passive and active) and neurological rehabilitation**
- Authors of medical **patents**.

A TEAM OF EXPERTS AT YOUR SERVICE

"A HIGHLY SKILLED WORK TEAM AND AN INTEGRATED APPROACH BOTH DURING THE ANALYSIS AND DEVELOPMENT PHASES."

MASSIMO ANTONINI

An engineer with many years of experience in the medical software development sector.
In addition to serving as Chairman of Polibrixia srl, he is the expert on all regulatory aspects related to the software such as risk analysis, the life cycle of medical software, the definition of architecture as well as the type of data communication.

ANTONIO BARTOLOZZI

Professor of "Design of medical device software and certification processes" at the University of Trieste.
He has designed several medical devices (ECGs, patient monitors for ICU therapy, telemedicine systems). In addition to his lecturing activities, he is a designer of healthcare and industry software, an independent auditor and expert operating on behalf of notified bodies, and consultant in the standardisation of medical devices.

ALDO DE GIULI

Decades of management experience accomplished in a broad spectrum of corporate positions.
He is a consultant, entrepreneur/partner, member of the Board of Directors in several SMEs and start-ups, in the medical sector, in ICT and much more. Former Vice-President of Assobiomedica, Services and Telemedicine, and a Member of the Council of the Federation of Assobiomedica (currently Confindustria Medical Devices).

DAVIDE FAUSTI

An engineer with many years of experience in mechanical design and multi-physics simulations, who is responsible for the Medical Devices division at Polibrixia srl.
He is the author of publications and research in the fields of "rehabilitation machines" and "disability aids", and the inventor of national and international patents.

MAURIZIO MOR

Mechanical engineer and project manager at Polibrixia.
After a doctorate focusing on the "design and engineering of a mechatronic device for the rehabilitation of the hand", he has also been coordinating innovative medical project development teams for many years. He also supports enterprises from a regulatory point of view in order to obtain EC markings according to the MDR Regulation (EC) 2017-745 and the management of their Quality System according to ISO 13485 standard requirements.

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TECHNICAL ASPECTS OF THE PROJECT

Our services are mainly designed to support companies in the development of innovative medical devices, providing the vital know-how required to address increasingly complex markets, regulated by highly specific and strict standards and regulations, such as the Medical Devices Regulation.

In such a complex technological and regulatory context, it is essential to identify the most suitable development strategies in good time.

In order to meet the requirements of current legislation and the rapidly changing market, it has become essential to be able to rely on an expert, specialised and multi-disciplinary project design, which can guide the customer towards the best strategic choices, from design to project execution.

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DESIGN CONSULTING SERVICES

Polibrixia Biomedical Engineering does not simply envisage compliance with all the regulations in force but, considering the constraints that arise from the early stages of the project life cycle, we also identify the best solutions for a swift and uninterrupted evolution of the product.

> Extensive knowledge of the regulatory framework encounters the multi-year experience in the biomedical, engineering, and management fields to efficiently meet the demands of our customers.

Our goal is to accompany the corporate projects of collaborating enterprises far beyond safety and performance requirements, to accomplish highly innovative medical devices step by step and state-of-the-art solutions for the demands of the future.

CE 0068

LEPRE

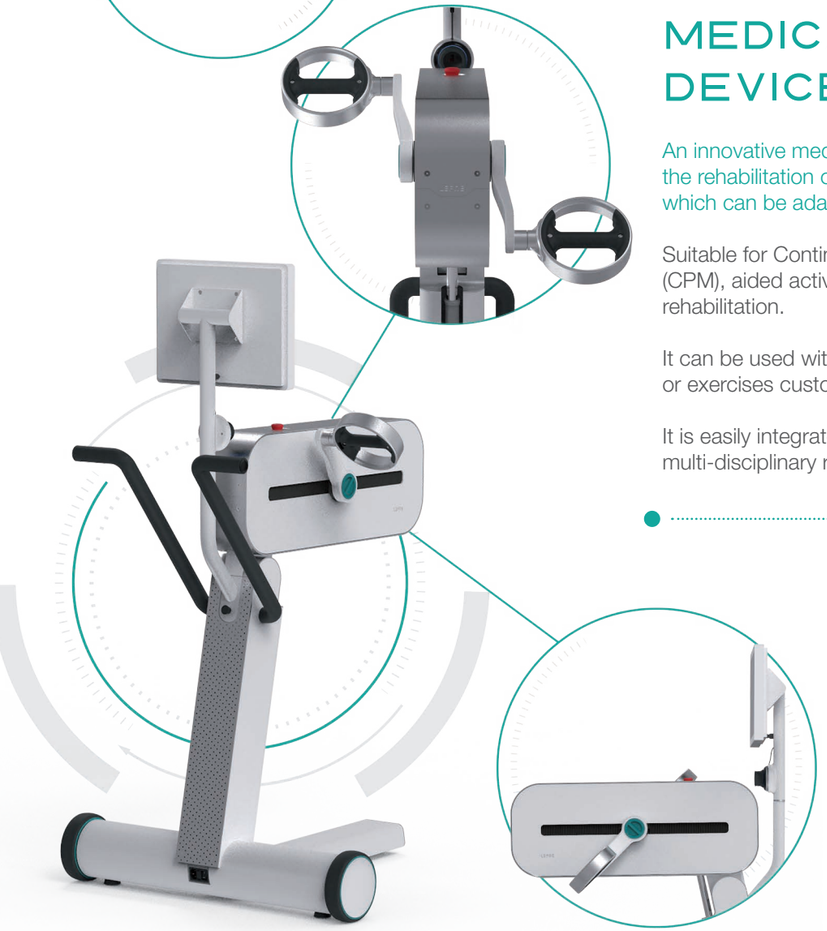
MEDICAL DEVICE

An innovative medical device used for the rehabilitation of the upper and lower joints, which can be adapted to suit the treatment.

Suitable for Continuous Passive Motion (CPM), aided active, active with biofeedback rehabilitation.

It can be used with pre-set exercises or exercises customised by the Clinic.

It is easily integrated within the multi-disciplinary rehabilitation project.



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