ENGINEERING IN MEDICAL TECHNOLOGY

mechatronics

innovation center

ISO 13485 CERTIFICATION

COMPLEX DEVICES FOR **MEDICAL TECHNOLOGY FIELD**

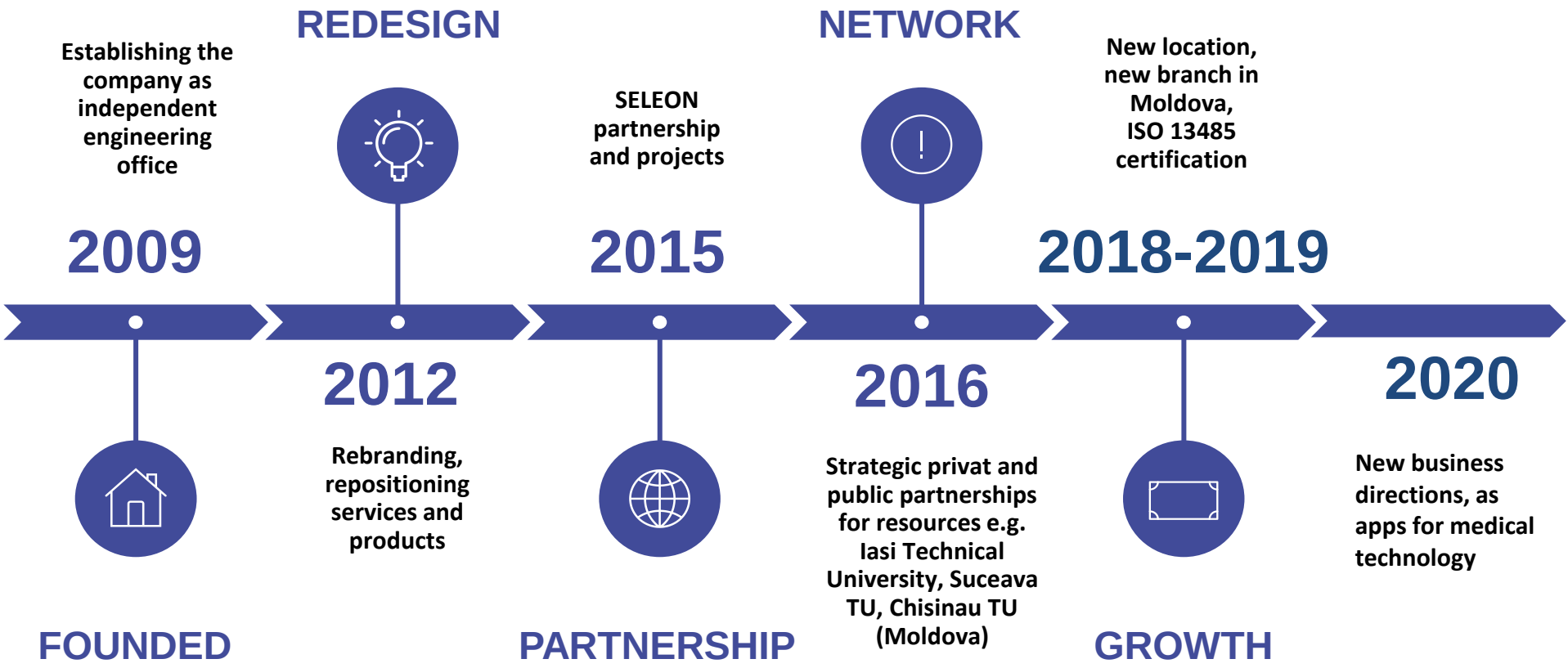
MISSION

Our team of experienced project managers, engineers, firmware and software specialists, consultants and our network of external support for specific needs find **innovative** solutions to ensure the **success** of our partners.

COMPANY HISTORY

The company was founded in 2009 by Mihai Murgulescu M.Sc., with almost 30 years of experience in medical technology and international expertise in project management, business development, research and development in this field.
From integrating software and firmware modules in bigger projects to developing own projects until turn-key delivery, complying with the current international standards in quality management, Mechatronics Innovation Center has continuously extended its competencies and its team, opening new business units and currently comprising about twenty full-time and project-based engineers and software developers.

COMPANY MILESTONES



EXPERTISE AREAS

- Embedded & PC software development
- Mobile and web application development
- Analog and digital electronic design
- Mechanical design and CAD modelling
- Requirement engineering
- Verification & Validation
- Regulatory affairs
- Project management

ISO 13485 CERTIFICATION

IQNet®

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SRAC *as an IQNet Partner hereby states that the organization:*

MECHATRONICS INNOVATION CENTER S.R.L.
Registered Office: Str. Actor Miluță Gheorghiu, nr. 2, Iași, jud. Iași

Productive Unit: B-dul Socola, nr. 206A - 208, sc. A, et. 6, Iași, jud. Iași

for the following scope:

Research, development, design and technical assistance for the realization of zero series, production, trials and attempts, installation, commissioning and service of non-active medical devices, active (non-implantable), in vitro diagnostics and incorporating / using specific substances

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2018 - 08 - 13
First issued on: 2018 - 08 - 13
for the validity date, please refer to the original certificate issued by* **SRAC**

Registration Number: RO - 104

IQNet

Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager

SR AC

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Certification *Finland* INTECO *Costa Rica* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland* Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* Vinçotte *Belgium* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

WHY WORKING TOGETHER

- Successful and proof record of completed projects
- International certifications
- Continuously active on the international market since 2009
- Complex abilities of professional communication and processing information
- Highest standards of quality, supported by successful long-term cooperation with German and Swiss clients, at fair, affordable prices

PARTNERS (SELECTION)

seleon
rock solid medical engineering

seleon gmbh
Heilbronn
Germany

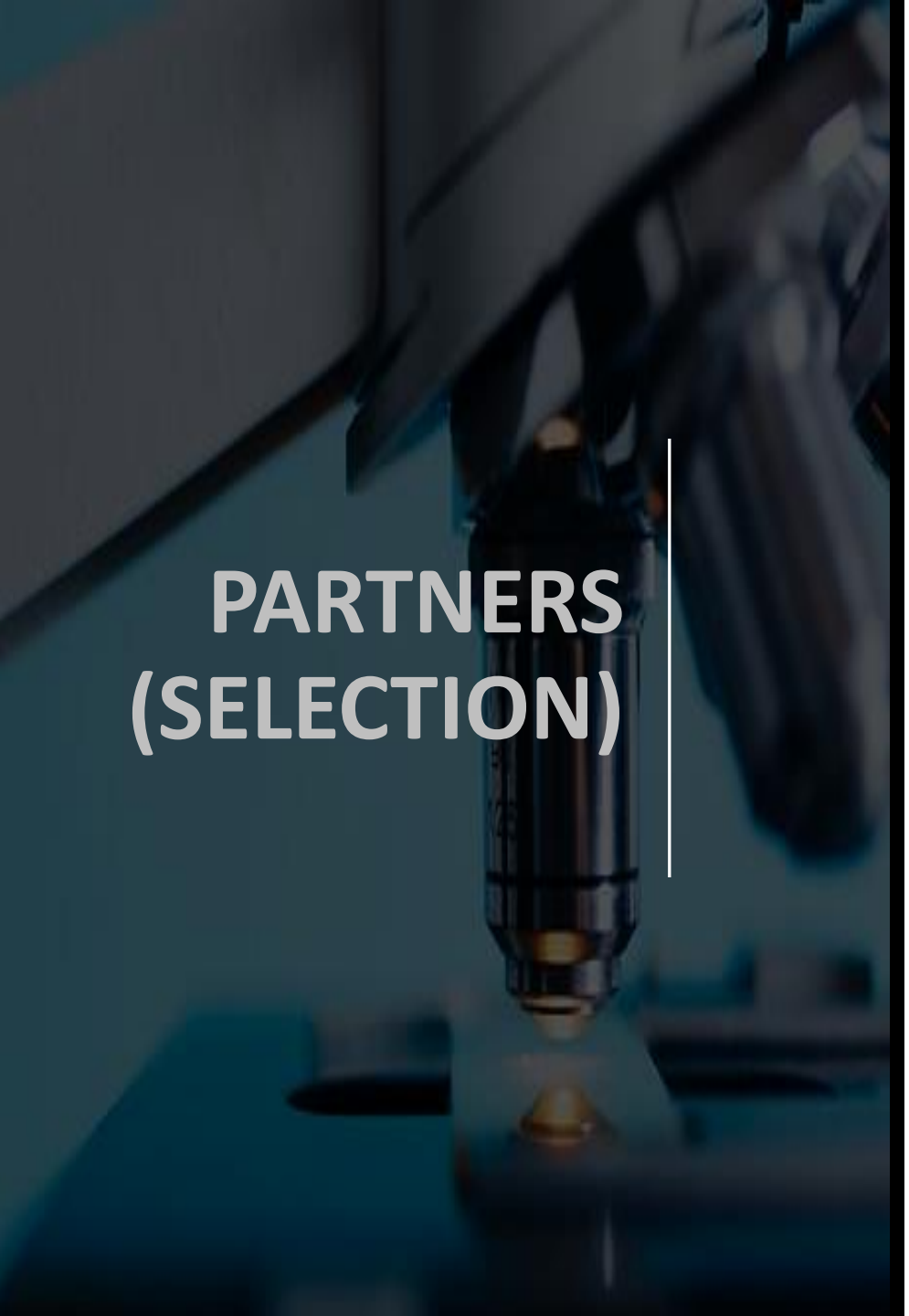
Technical
University of
Iasi

USV

Technical
University of
Suceava

UTM

Technical
University
of Moldova



PARTNERS (SELECTION)

The Technical University ‘Gh. Asachi’ Iasi has proved itself a proactive partner in recruiting young engineers and masterands. Other valuable resources are provided by the Technical University ‘Ștefan cel Mare’ from Suceava, the ’Grigore T Popa’ University of Medicine and Pharmacy in Iasi, through the Faculty of Medical Bioengineering and the Technical University of Moldova from Chişinău as well.

2018 ESTABLISHING MIC MOLDOVA

Mobility of team members, shared expertise and experience, professional management team with relevant international training and experience.

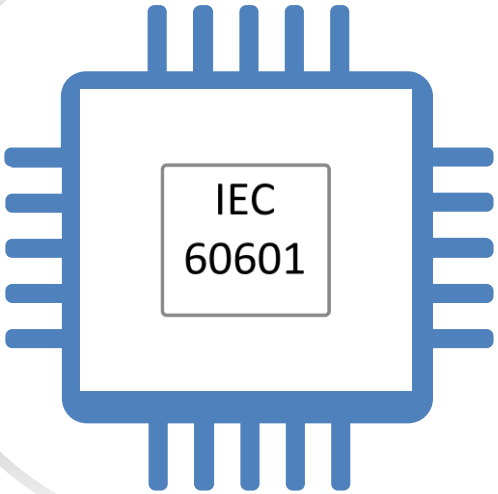
Implementation of an international quality management system

TEAM

The team consists of young and enthusiastic engineers which work together with experienced colleagues. Since company foundation numerous international projects have been successfully run. With our team, each of our projects reaffirms our ambition to find innovative solutions and help our partners succeed in the market. In complex projects, needing specific expertise, we complete our resources with partner companies. Our common workflow is well-run in many projects.

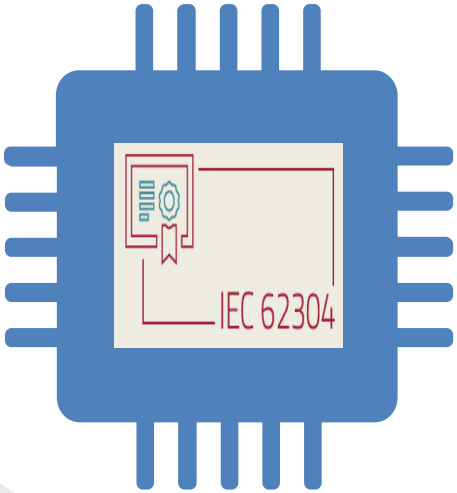
ELECTRONIC DEVELOPMENT

- Component Selection and Evaluation
- Functional Model Building
- PCB Schematics
- PCB Layout
- PCB Set-up and Design Transfer to Production



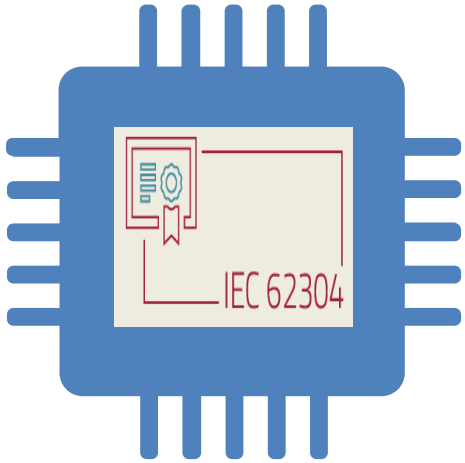
FIRMWARE DEVELOPMENT

- Business Process Analysis; Requirement Creation
- Architecture ; Detailed Design
- Coding
- Automated Testing
- Item and System Integration



SOFTWARE DEVELOPMENT

- Business Process Analysis; Requirement Creation
- Architecture, Detailed Design
- Coding
- Automated Testing
- Item and System Integration



COMPLETED PROJECTS (SELECTION):

- Battery powered handheld device.
- Intelligent DC power sources: tissue parameter recognition, adaptive therapy currents
- Monitoring and display of total applied electrical charge per treatment

Development of a complete innovative prostate treatment device

COMPLETED PROJECTS (SELECTION):

- Software architecture for safety microcontroller
- Implementation
- Unit testing

Development of an embedded software safety module for an Automatic External Defibrillator

COMPLETED PROJECTS (SELECTION):

- Complete electronic, embedded and PC software development
- Electronic motherboard for sensors and motion control
- DC motor drives for precise massage jet positioning
- Variable Frequency Drive for water jet pump control
- 10” touch screen display HMI with personalized multi-layer menus
- RS-485 Full Duplex communication between motherboard and HMI module

Development of a water jet massage system (electronics, embedded software, Human Machine Interface)

COMPLETED PROJECTS (SELECTION):

- Distributed architecture using multiple microcontrollers connected through an CANopen bus
- Development of a 7 degrees of freedom motion control algorithm
- Ultrafast step motor driver control
- Jacobian motion transformation algorithms
- CANopen communication protocol

Development of an embedded software concept and software implementation for a chirurgical robot

COMPLETED PROJECTS (SELECTION):

- Real time automatic exposure and pattern recognition algorithms
- Code optimization for intensive usage of all microprocessor resources
- Data export via BTLE and SD card

Development of an image acquisition, processing, and pattern recognition embedded software for medical diagnose screening

COMPLETED PROJECTS (SELECTION):

- Cloud solution with multiple user groups using Amazon Web Services (AWS) cloud platform.
- Mobile App solutions for Android and iOS with complex multi-layer HMIs
- Real time transmission of secure video and audio signals
- Real time warning system from patient via cloud to supervisor

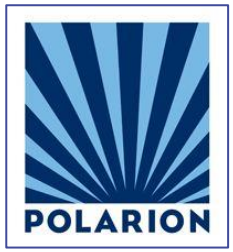
Mobile Applications and Cloud Software development for a remote patient video, audio and vital parameters monitoring system

COMPLETED PROJECTS (SELECTION):

- Pump drivers, motor drivers, positioning algorithms
- Patient motion detection algorithms
- Power management
- Software and hardware emulators and testing environments

Development of different electronic and software modules for Negative Pressure Wound Therapy (NPWT) devices, contrast agent injector and x-ray diagnostic devices.

TOOLS AND PLATFORMS



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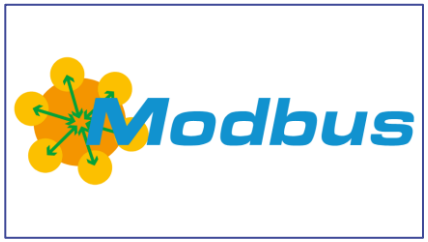

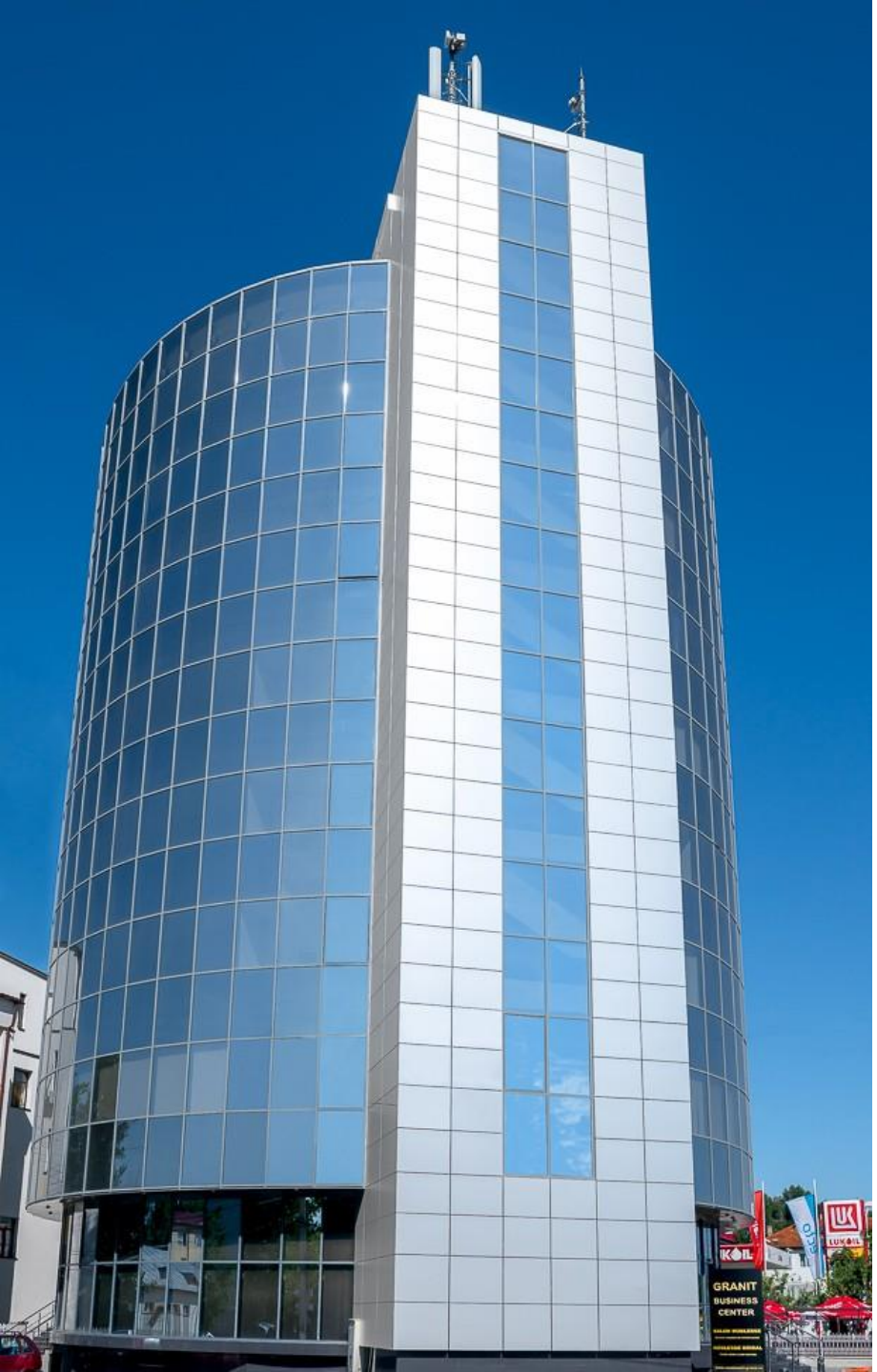

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