ECM for Medical Devices

EUROPEAN NOTIFIED BODY #1282

About ECM

OUR **HISTORY**

Since 1996, ECM - Ente Certificazione Macchine helps companies to verify compliance with the standards imposed by several EU Directives.
ECM is a **NOTIFIED BODY** and **ACCREDITED TESTING LABORATORY**, to offer many option for **QUALITY** and **SAFETY** related services.

The **ECM family** is made of many branches and partnerships across the world: **Italy** (headquarters), USA, China, South Korea, Japan, Israel, India, Argentina, Mexico and Brazil.

OUR **ACCREDITATIONS**

- ✓ **Notified Body #1282** for EU Product Directives:
  Medical Devices, Machinery, EMC, Noise Emission, Atex, PED, Lifts
- ✓ **QMS** ISO 9001 & ISO 13485 **Certification Body**
- ✓ Accredited **Testing Laboratory** ISO 17025
- ✓ **NCB & CBTL** within IECEE CB Scheme
- ✓ **Inspection** and **Training** Body

OUR **MISSION**

ECM helps manufacturers to bring **safe** and **quality** medical devices to the global market, through an efficient certification and testing service. Our goal is to simplify the market journey, promote innovation and safety, and improve the MD field.

OUR **VALUES**

Ethics and Integrity
Commitment and responsibility
Innovation and creativity
Improvement and professional growth

OUR **STRENGHT**

Efficiency - Solutions tailored to your needs
Time to Market - Approvals in weeks rather than months
Experience - a Team of experts for testing, audit and certification

ECM for Medical Devices

WHAT WE DO for Medical Devices

- ✓ CE Certification
- ✓ QMS ISO 13485 & 9001 Certification
- ✓ Testing Lab Service
- ✓ Training courses
- ✓ International Approvals
- ✓ Rush Services for CE and ISO

ECM for Medical Devices

Road Map

EU MDR

Application submission on **December 15th 2018**

MDSAP

Application preparation **First half of 2019**

IVDR

Application preparation **Late 2019 / 2020**

OUR SERVICES

Standard Certification Structure

As a **Notified Body for MDD 93/42/CE**, ECM is designated to review the conformity of medical devices to the MDD requirements for access to the EU market.

CE Certification

Certification for Quality Management Systems

As **Notified Body for Quality Management System Certification**, ECM can deliver QMS Certifications, according to the following standards:

- ✓ EN ISO 9001:2015
- ✓ EN ISO 13485:2012
- ✓ EN ISO 13485:2016

Our Quality Management services for the medical device industry include **auditing**, **inspection**, **testing**, **quality assurance** and **certification**.

QMS Certification

Testing service in our **Accredited Testing Lab**

ECM is an **NCB & CBTL** and an **Accredited Testing Laboratory ISO/IEC 17025,** able to carry out testing activities for your medical devices according to the IEC/EN-60601 standard.

The **IEC/EN-60601** standard is widely accepted internationally for the basic safety and essential performance of medical electrical equipment. The compliance to requirements of EN 60601 is fundamental for all manufacturers of **Medical Electrical Equipment** who want to sell their devices in Europe.

We test compliance for:

- ✓ **Electric Safety**
- ✓ **EMC** (Electromagnetic Compatibility)
- ✓ **Performance**
- ✓ **Grade IP**

Our Laboratory provides

Debug Activity Service

to solve specific issues

TESTING

ECM ACADEMY

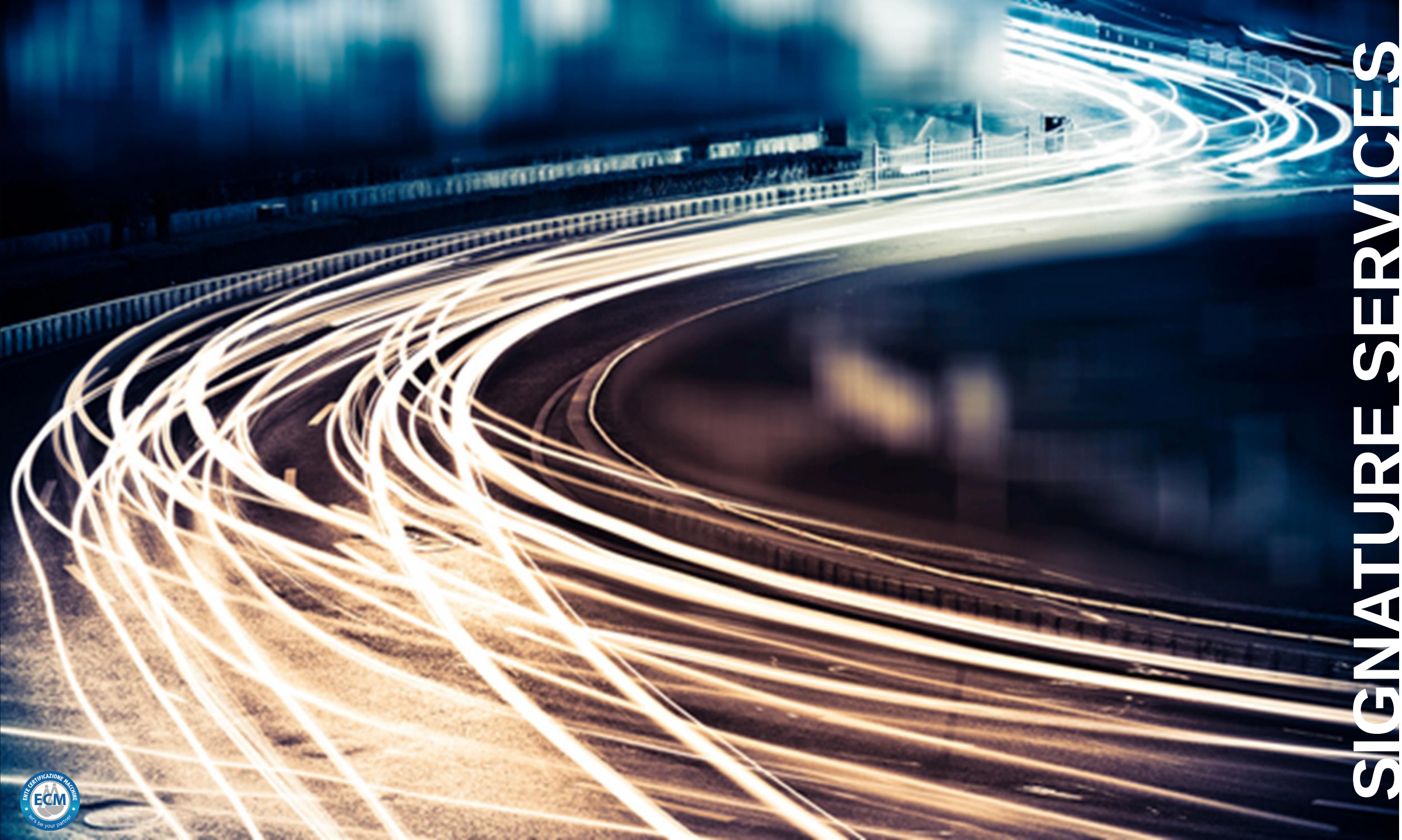
Training Service for Regulatory Issues

TRAINING

Our **high-quality Training Service** is designed to help companies and professionals to improve their **competence and skills**, in order to increase core business and competitive advantage.

ECM's **experts** provide **tailored learning experiences**, according to your needs – **public or in-house** – to update your staff on the latest developments on technology, standards and regulations. Our main courses includes:

- ✓ Transitioning to the new MDR EU 2017/745
- ✓ Best practices for QMS ISO 13485 & 9001
- ✓ Best practices for Technical Documentation
- ✓ Best practices for Clinical Evaluation Reports (CER)
- ✓ Other regulatory issues


SIGNATURE SERVICES

THE **TIME TO MARKET** IS IN THE **CLIENT'S HANDS**

Our Signature Services offer clients innovative solutions to speed up their certification process, compared to our regular **CE and ISO Certification** services.

HOW WE ACHIEVE IT

Thanks to our **dedicated project team**, composed by product experts, clinical experts and a lead project manager, we can shorten our technical times to deliver your reviews and report.

THE KEY FOR SUCCESS

These services are based on a mutual **collaboration** between the NB and the Manufacturer. In order to perform our part, we need the client to provide well-prepared and complete documentation, and to be proactive in responding to the possible NCs detected.

SIGNATURE Services

ECM's EXPRESS SERVICE significantly shortens the technical timings of the CE and ISO 13485 Certification processes.

This service provides clients with more **flexibility** in the schedule of their certification process, allowing them to plan and organize regulatory, market and production activities.

PHASE 1 TECHNICAL REVIEW	**PHASE 2** ON-SITE AUDIT	**PHASE 3** FINAL REVIEW & CERTIFICATION
Review Report of TCF, CER and QMS Manual	On-Site audit for QMS	Final review and deliberation of Decision Maker Committee
in 10 WORKING DAYS	**in 15 WORKING DAYS**	**in 5 WORKING DAYS**
from the receipt of the Technical Documentation	from the closure NCs of Phase 1	from the closure NCs of Phase 2

EXPRESS Service

ECM's ON TIME SERVICE is the best solution for the clients' needs of CE and ISO 13485 regulatory approval.

The On Time Service is **EXECUTED ON SITE**, our Experts will visit the manufacturer's premises for an adequate period of time to finalize Phase 1 and Phase 2.

PRE-ASSESSMENT: Initial Evaluation of the Technical Documentation to assess if the On Time is the right fit for the client, and kick-off the project.

PHASE 1
ON-SITE TECHNICAL REVIEW

Review of TCF, CER and QMS Manual are done

ON-SITE

to engage in a dynamic discussion with RA of manufacturer to clear doubts and find solutions in real time

PHASE 2
ON-SITE AUDIT

On-Site audit for QMS

Scheduled once Phase 1 is completed

to engage in a dynamic discussion with RA of manufacturer to clear doubts and find solutions in real time

PHASE 3
FINAL REVIEW & CERTIFICATION

Final review and deliberation of Decision Maker Committee

in 5 WORKING DAYS

from the closure NCs of Phase 2

ON TIME Service

BENEFITS of ECM's Signature Services

Express Service

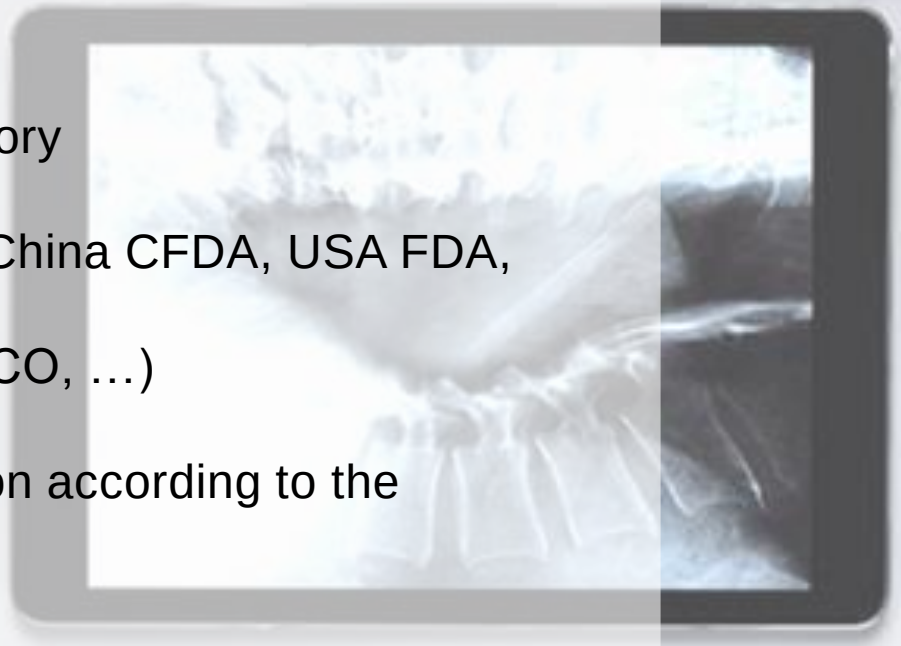
- ✓ Earlier revenues
- ✓ Avoid losing market share to competition
- ✓ Human resources working less time on certification issues
- ✓ Competitive advantage against competitors

On Time Service

- ✓ No misunderstandings
- ✓ Open discussion on corrective actions to be undertaken
- ✓ Empowering clients for future certifications

SIGNATURE Services

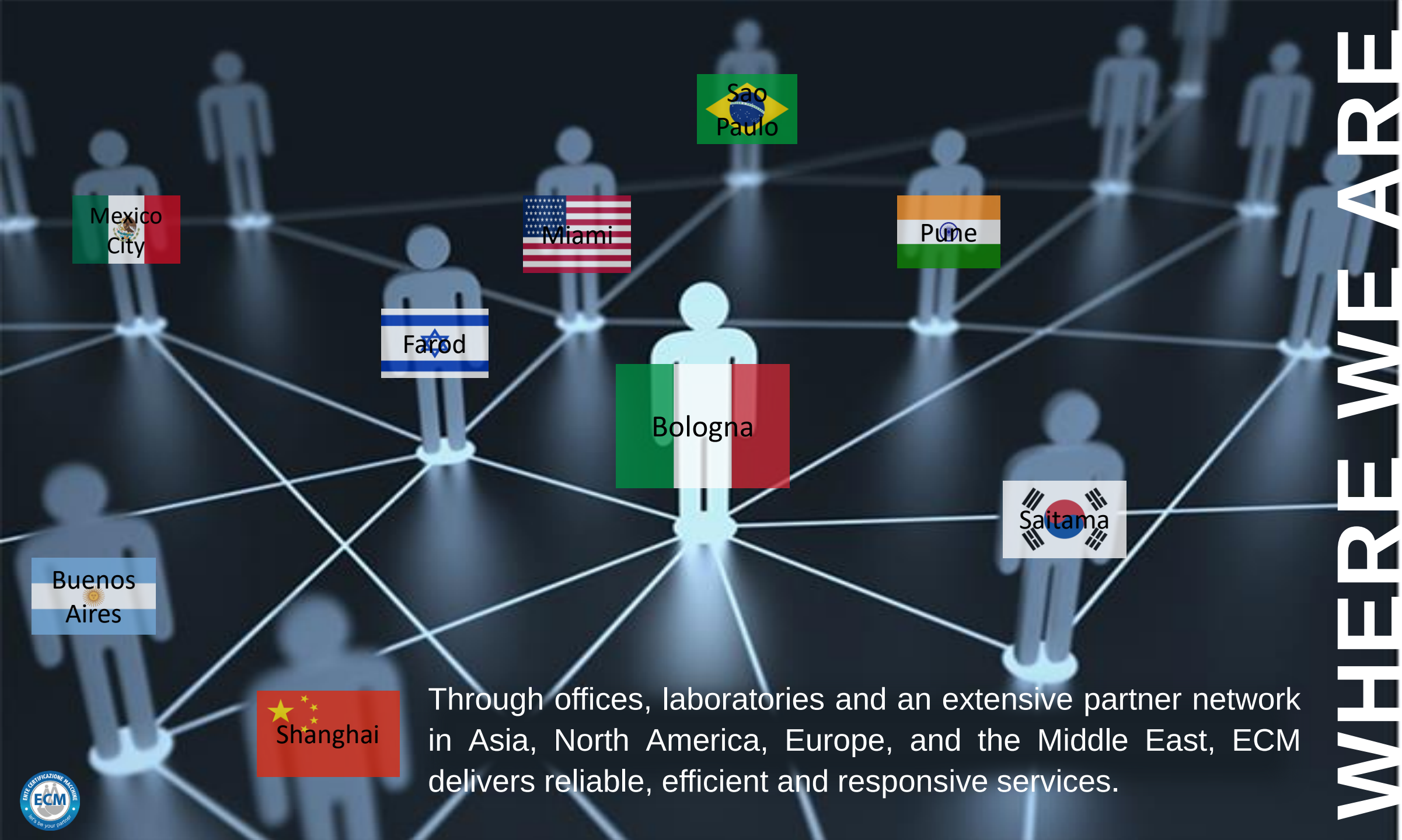
WHY choosing ECM



- ✓ Fast, efficient and professional support for **CE and ISO 13485** Certification
- ✓ Accredited ISO 17025 **Testing** Laboratory
- ✓ Support for **International Approvals** (China CFDA, USA FDA, Korea KFDA, Japan PMDA, India CDSCO, …)
- ✓ **NCB** & **CBTL** for testing and certification according to the international **IECEE CB** Scheme
- ✓ Faster market access through our **Signature Services**

ECM for Medical Devices

WHERE WE ARE



Through offices, laboratories and an extensive partner network in Asia, North America, Europe, and the Middle East, ECM delivers reliable, efficient and responsive services.

CONTACT US

ANTONIO BALASSONE
Sales Manager
Phone: +39 051 6705141
Mobile: +39 393 2471040
Email: antonio@entecerma.it
LinkedIn: /antoniobalassone/

ECM ITALY – Ente Certificazione Macchine
Address: via Ca' Bella 243, Valsamoggia (BO)
Phone: +39 051 6705141
Email: info@entecerma.it
Website: www.entecerma.it | www.ecmamerica.com

THANK YOU FOR YOUR TIME