ECM for Medical Devices

EUROPEAN NOTIFIED BODY #1282

Last update 09.11.2022

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), UK, USA, China, South Korea, Singapore, Vietnam, Turchia, India, Iran.

Our **ACCREDITATIONS**

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

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ECM for Medical Devices

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 - high professional services and customer care
Time to Market – a safe, fast and quality service
Experience - a Team of experts for testing, audit and certification

WHAT WE DO for Medical Devices

- ✓ EU Certification
- ✓ Training courses
- ✓ QMS ISO 13485 & 9001 Certification
- ✓ International Approvals
- ✓ Testing Lab Service
- ✓ Express Service

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OUR SERVICES

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Standard Certification Process

As a Notified Body for **Medical Device Regulation (EU) 2017/745**, ECM is designated to assess the conformity of medical devices to the MDR requirements for placing on the EU market.

PHASE 1

Application + Review

- Technical File
- CER
- QMS documents
- Test Reports

PHASE 2

On Site Audit

QMS ISO 13485

PHASE 3

Final Review

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EU Certification

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Follow-up

Surveillances

CE Certification

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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 13485:2021

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

QMS Certification

Testing service in our **Testing Lab**

ECM is an **Accredited Testing Laboratory ISO/IEC 17025**, able to carry out testing activities for your medical devices according to the IEC/EN-60601 standard. *[To see the complete list of tests for which ECM is accredited, visit the following link]*

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** has been designed to allow companies and professionals to improve their skills in order to operate with greater efficiency and professionalism.

ECM **experts** provide **training courses** in classroom or in e-learning mode.
Our courses focus on the major and most recent regulatory issues, in order to offer participants a highly professionalizing experience. Among the topics covered:

- ✓ The new Regulation MDR EU 2017/745
- ✓ The CE marking process of a medical device
- ✓ The Certification of the Quality Management System according to ISO 13485
- ✓ standard
- ✓ Other technical or regulatory topics

SIGNATURE SERVICES

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THE **RESULT** IS IN THE **CLIENT'S HANDS**

Our **Signature Services** offer clients innovative solutions, compared to our regular **EU e ISO Certification** services.

HOW CAN WE ACHIEVE IT

Thanks to our **dedicated project team**, composed by product experts, clinical experts and a lead project manager, we can optimise the planning of activities, with greater flexibility in scheduling the certification process.

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

Our **EXPRESS SERVICE** assigns a dedicated team of professionals to the client.

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 DOCUMENTAL REVIEW	**PHASE 2** ON-SITE AUDIT	**PHASE 3** FINAL REVIEW & CERTIFICATION
Review Report of TCF, CER and QMS documents	On-site Audit for QMS	Final review and deliberation of the Issuance of the Certificate
from the receipt of the Documentation	from the closure NCs of Phase 1	from the closure NCs of Phase 2

EXPRESS Service

Our **ON TIME SERVICE** is the best solution for the clients' needs of EU 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: Preliminary Evaluation of the Technical Documentation to assess if the On Time Service is appropriate for the customer and if the conditions to start the project are met.

PHASE 1
ON-SITE DOCUMENTAL REVIEW

The Review of TCF, CER and QMS documents are executed

ON-SITE

in a dynamic discussion with the RA of manufacturer

PHASE 2
ON-SITE AUDIT

On-Site Audit for QMS

Scheduled once Phase 1 is completed

in a dynamic discussion with the RA of manufacturer

PHASE 3
FINAL REVIEW & CERTIFICATION

Final review and deliberation of the Issuance of the Certificate

from the closure NCs of Phase 2

ON TIME Service

BENEFITS of ECM's Signature Services

Express Service

- ✓ Allocation of a team of professionals
- ✓ Greater flexibility in scheduling the certification process
- ✓ Optimal planning of staff deployment in certification activities

On Time Service

- ✓ No misunderstandings
- ✓ Dynamic discussion and immediate response to any questions
- ✓ Empowering clients for future certifications

SIGNATURE Services

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WHY choosing ECM

- ✓ Fast, efficient and professional support for **EU** and **ISO 13485** Certification
- ✓ Accredited ISO 17025 **Testing** Laboratory
- ✓ Support for **International Approvals** (China CFDA, USA FDA, Korea KFDA, Japan PMDA, India CDSCO, …)
- ✓ Advantages through our **Signature Services**

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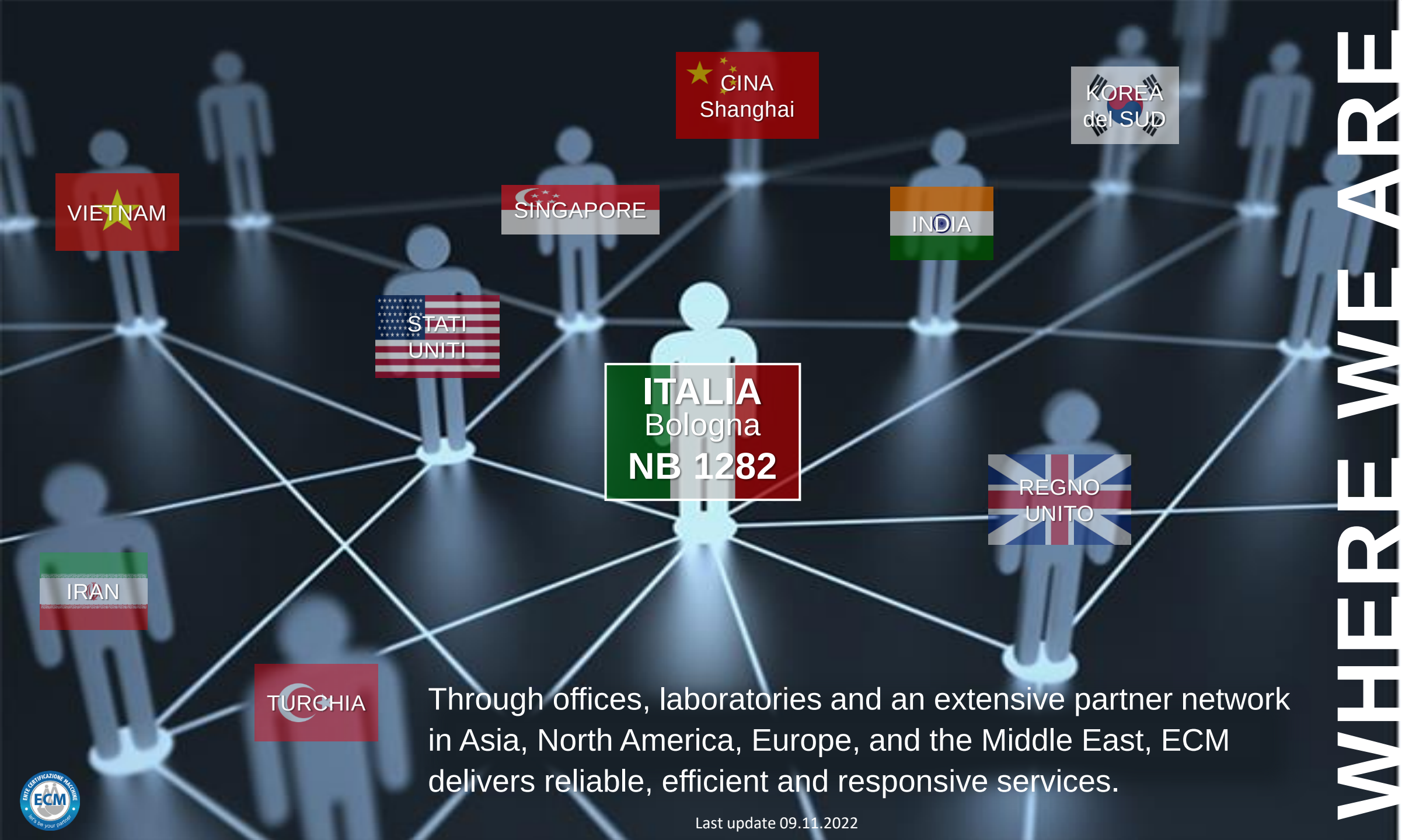

WHERE WE ARE

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

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CONTACT US

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