



ECM for Medical Devices

EUROPEAN NOTIFIED BODY #1282

Last update 11.09.2020

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, RED, 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 STRENGTH

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

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



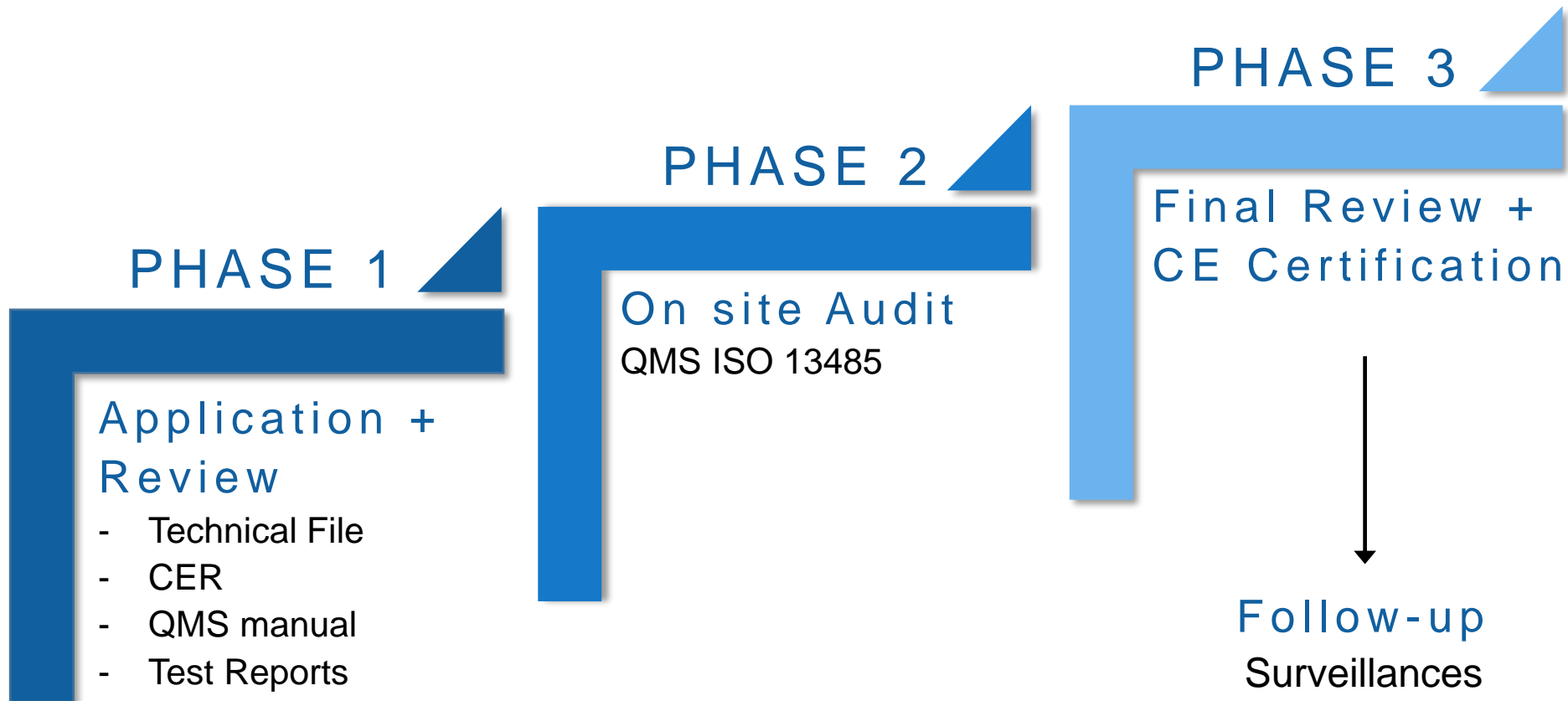
OUR SERVICES



Last update 11.09.2020

Standard Certification Process

As a Notified Body for MDD 93/42/CE, ECM is designated to assess the conformity of medical devices to the MDD requirements for placing on 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 13485:2016

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

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, on site at the applicant company 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

TRAINING





SIGNATURE SERVICES



Last update 11.09.2020

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.

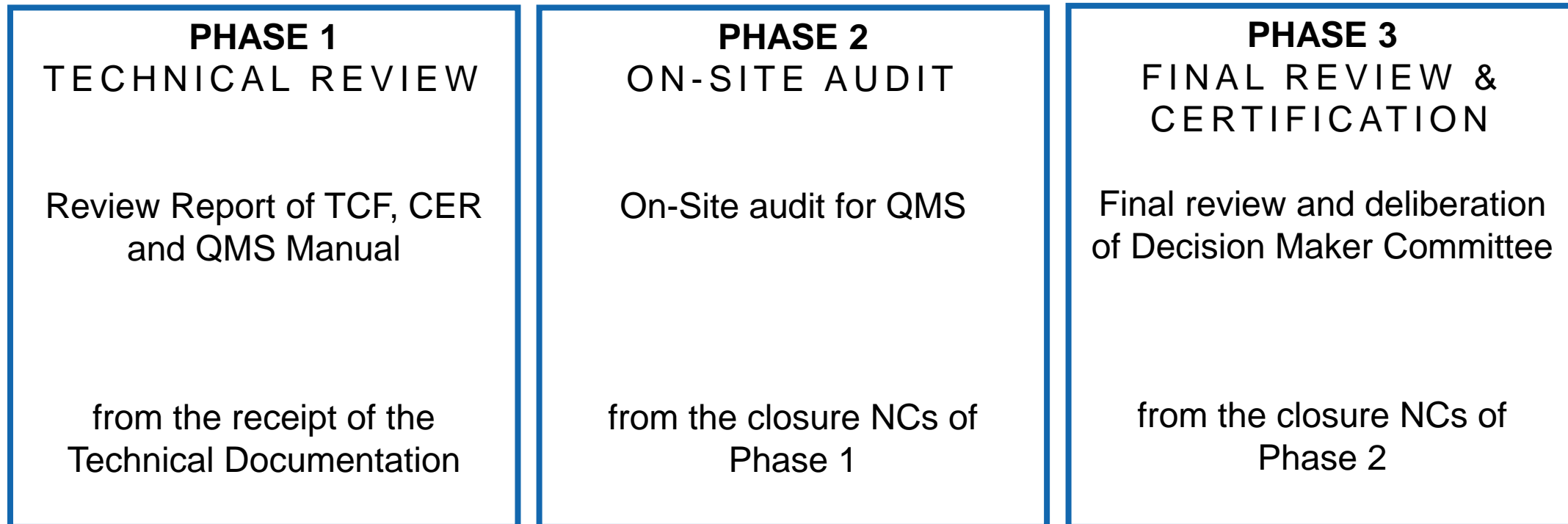
THE KEY FOR SUCCESS

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.



Our **EXPRESS SERVICE** significantly reduces the technical time of the CE and ISO 13485 certification processes, thanks to the assignment of a dedicated team of professionals.

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.



EXPRESS SERVICE



Our **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: 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 TECHNICAL REVIEW

The Review of TCF, CER and
QMS Manual 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 Decision Maker Committee

**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
- ✓ Dynamic discussion and immediate response to any questions
- ✓ Empowering clients for future certifications

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**

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.

Last update 11.09.2020



CONTACT US



ANTONIO BALASSONE

Sales Manager

Ph.: +39 051 6705141

Mob.: +39 393 2471040

Email: antonio@entecerma.it

LinkedIn: /antoniobalassone/



ECM ITALY – Ente Certificazione Macchine

Address: via Ca' Bella 243, Valsamoggia (BO)

Ph.: +39 051 6705141

Email: info@entecerma.it

www.entecerma.it

THANK YOU FOR YOUR TIME

