

# Global Medical Device Regulatory Expertise

## CE Marking, FDA & Beyond.

A specialist medical device regulatory consulting firm covering FDA 510(k), CE marking under EU MDR, UK MHRA, ISO 13485 and GCC registration. Share your device and target markets, and we map the fastest, most cost-effective route to approval.



Trusted by 200+ life sciences companies worldwide



## Your Specialist Device Partner



### One specialist partner for the entire device lifecycle.

RABT Global is a specialist medical device regulatory consulting firm covering FDA 510(k), CE marking under EU MDR, UK MHRA, ISO 13485 and GCC registration. We combine deep regulatory expertise with a client-first approach, helping manufacturers of Class I to III devices and IVD Class A to D products reach the markets they are aiming for.

**500+**

Device submissions

**40+**

Countries covered

**17**

Device services

**5+**

Years of experience

### WHY MANUFACTURERS CHOOSE RABT GLOBAL



#### A single specialist partner

One team for strategy, submissions and post-market, with no outsourcing or fragmentation.



#### Dedicated specialist teams

Dedicated teams for FDA, EU MDR, ISO 13485 and CER clinical science.



#### Parallel submissions

Coordinated submissions across FDA, EU MDR, MHRA and GCC to shorten market entry timelines.



#### Regulatory intelligence

Proactive monitoring of changing device rules, so changes never catch your programme off guard.

### DEVICE TYPES WE COVER



#### Implantables

Orthopaedic, cardiovascular, neuromodulation and ophthalmic implants.



#### IVD / diagnostics

Molecular, point-of-care, immunology and serology, and companion diagnostics.



#### SaMD / digital health

AI/ML devices, clinical decision support, wearable monitors and patient apps.



#### Combination products

Drug-device and biologic-device products, FDA jurisdiction strategy and EU borderline assessment.

## Four Regions. One Specialist Team.

EU MDR

GCC

Regulatory expertise for the markets your device is aiming for.

FDA

### United States

FDA

- + 510(k), PMA, De Novo
- + US FDA Agent services
- + Device classification

EU

### Europe

EU MDR / IVDR

- + CE marking, MDR and IVDR compliance
- + Clinical Evaluation Reports (CER)
- + Post-market surveillance
- + EU Authorised Representative

UK

### United Kingdom

MHRA

- + MHRA registration
- + UKCA marking support
- + Post-Brexit device compliance
- + MHRA liaison

GCC

### Middle East

GCC

- + UAE MOHAP and Saudi SFDA
- + Kuwait, Qatar, Bahrain and Oman registration
- + GCC MRA strategy

## THE DEVICE LIFECYCLE, COVERED END TO END

### Stage 1

#### Classification & strategy

- Device classification
- Pathway selection
- Pre-submission strategy
- Market entry roadmap

### Stage 2

#### Technical documentation

- 510(k) dossiers
- EU MDR Technical Files
- CE technical documentation
- ISO 13485 QMS implementation

### Stage 3

#### Clinical evidence

- Clinical Evaluation Reports
- PMCF plans
- Equivalence assessment
- Literature review strategy

### Stage 4

#### Submission & approval

- FDA 510(k), PMA and De Novo filings
- CE conformity assessment
- EUDAMED registration
- Health authority liaison

### Stage 5

#### Post-market compliance

- Post-market surveillance
- PMSR / PSUR reporting
- Vigilance and FSQA
- Lifecycle submission management

**Parallel market entry.** We run submissions across FDA, EU MDR, MHRA and GCC in parallel, reusing data wherever possible, to shorten your time to market.

# EU MDR & CE Marking

EU MDR

**CE marking for medical devices, simplified.** CE marking is the route to the European medical device market, and under EU MDR 2017/745 the requirements are stricter than before. Without it, a device cannot legally be sold in the EU, the EEA or countries that accept CE-marked products.

## THE 5-STEP CE MARKING PROCESS UNDER EU MDR



## CONFORMITY ASSESSMENT ROUTES

| DEVICE                                                             | ROUTE                                                                                                                         |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| <b>Class I (non-sterile, non-measuring, non-reusable surgical)</b> | Annex IV self-certification. No Notified Body. Manufacturer prepares technical documentation and a Declaration of Conformity. |
| <b>Class I sterile, measuring or reusable surgical</b>             | Annex IV plus specific Annex involvement. Notified Body required only for sterility or measuring function.                    |
| <b>Class IIa and IIb</b>                                           | Annex IX (QMS) plus Annex II/III technical file, or Annex X plus Annex XI type examination. Notified Body required.           |
| <b>Class III and IIb implantables</b>                              | Annex IX design dossier examination plus Annex X and XI. Notified Body design examination required.                           |

## OUR EU MDR SERVICES



**Legacy MDD devices:** extended deadlines apply: 31 December 2027 for certain Class IIb implantable devices and 31 December 2028 for certain Class IIa and Class I devices with MDD history. We confirm the deadline for your device and build your transition roadmap.

## EU IVDR & Device Classification



IVDR

**IVDR 2017/746 replaced the IVDD, so IVD products need full IVDR compliance.** That means reclassification, new performance evaluation, updated documentation, EUDAMED and UDI, and usually Notified Body involvement. Notified Body capacity is constrained, so early engagement matters.

### OUR 6-STEP IVDR ROUTE

1

#### Portfolio assessment & classification

Classify IVDs under Annex VIII, identify Notified Body needs by class and map a timeline per device.

2

#### Gap analysis & remediation plan

Assess documentation, performance data and QMS, then build a prioritised remediation plan.

3

#### Performance evaluation & PMPF

Plan and review analytical and clinical studies, prepare the Performance Evaluation Report and a PMPF plan.

4

#### Technical documentation

Compile device description, labelling/IFU, performance evaluation, risk management and QMS evidence.

5

#### Notified Body application & audit

Select an IVDR-scoped Notified Body, submit the application and prepare for technical review and audit.

6

#### EUDAMED, UDI & CE marking

Register in EUDAMED, assign UDI, issue the Declaration of Conformity, affix the CE mark and begin PMPF and vigilance.

✓ Common Specifications compliance review

🔗 Companion Diagnostic (CDx) IVDR strategy

**Missed or approaching a deadline?** We offer an urgent assessment, a prioritised programme and an accelerated Notified Body application. Transition timelines depend on device class, and we confirm the deadline for each IVD in your portfolio.

### MEDICAL DEVICE CLASSIFICATION

Incorrect classification can derail an entire regulatory strategy. We deliver a classification report with the outcome, the requirements and the recommended conformity route.

| FRAMEWORK | WHAT WE COVER                                                              |
|-----------|----------------------------------------------------------------------------|
| FDA (US)  | Rule of thumb and 513(g) determinations for Class I, II and III devices    |
| EU MDR    | Annex VIII rule-based classification into Classes I, IIa, IIb and III      |
| EU IVDR   | Classification of in vitro diagnostic devices into Classes A, B, C and D   |
| UK MHRA   | Classification under UK MDR 2002 (amended) for Great Britain market access |
| GCC       | Requirements for UAE MOHAP, Saudi SFDA and other GCC markets               |

# FDA 510(k) & US Market Entry

De Novo

**The gateway to the world's largest medical device market.** The 510(k) is the FDA's main premarket pathway for Class II devices: you show that your device is substantially equivalent to a legally marketed predicate. Typical timelines run 6 to 14 months, depending on Q-Sub use, testing complexity and any FDA information requests.

## OUR 6-STEP 510(K) PROCESS



## CHOOSING THE RIGHT FDA PATHWAY

| PATHWAY | DEVICE CLASS   | PREDICATE NEEDED | CLINICAL DATA      | BEST WHEN                      |
|---------|----------------|------------------|--------------------|--------------------------------|
| 510(k)  | Class II       | Yes              | Often not required | A valid predicate exists       |
| De Novo | Novel Class II | No               | Sometimes          | The device is truly novel      |
| PMA     | Class III      | No               | Pivotal study      | Life-sustaining or implantable |

## US FDA AGENT SERVICES



### Your statutory US Agent for foreign manufacturers

- US Agent designation in FDA systems (FURLS)
- FDA correspondence received and forwarded within 24 hours
- Import alert support
- Annual establishment registration management
- Contact for FDA inspection pre-announcements
- Proactive monitoring of FDA enforcement activity

Post-clearance support includes establishment registration, device listing and publication of the 510(k) summary. We also support PMA and De Novo submissions.

## ISO 13485, UK & Post-Market

ISO 13485

UKCA

MDSAP



### ISO 13485: your foundation for global medical device market access.

ISO 13485:2016 is the quality management system standard for medical device manufacturers worldwide, and the basis of the Notified Body QMS assessment for Class IIa, IIb and III devices under EU MDR.

1

#### Gap analysis

Free call: we review your current system and identify the gaps.

2

#### QMS implementation

Right-sized, scalable systems, from startups to established manufacturers.

3

#### MDSAP alignment

One audit route covering FDA, Health Canada, TGA, ANVISA and PMDA.

4

#### Audit preparation

Certification audit readiness, aligned with MDR Annex IX.

### UK MHRA



#### MHRA registration and post-Brexit compliance

Great Britain operates under MHRA's independent framework, separate from EU MDR, while Northern Ireland follows EU rules under the Windsor Framework. We plan GB and Northern Ireland access together.



UKCA marking support



MHRA registration



UK MDR 2002 classification



MHRA liaison

### CLINICAL EVIDENCE AND POST-MARKET



#### Clinical Evaluation Reports

- + CER preparation to EU MDR Annex XIV
- + PMCF plans
- + SSCP and literature search
- + Equivalence assessment



#### Post-market surveillance

- + PMS plans
- + PMSR and PSUR reporting
- + Vigilance and FSCA
- + Retainer model for ongoing support

# RABT

TRUST & CONTACT

## Why Clients Trust RABT Global



Qualified regulatory affairs professionals with RAC, MSc and PhD credentials



ISO-compliant quality management systems for all regulatory deliverables



Member of TOPRA (The Organisation for Professionals in Regulatory Affairs)



Experience across FDA, EMA, MHRA, CDSCO, SFDA and Health Canada frameworks



Transparent project management with a dedicated account manager per client



Confidentiality protected by signed NDAs across all engagements



RABT Global transformed our regulatory approach. Their team managed our EU MDR submission from gap analysis to CE mark efficiently and on schedule. We couldn't have achieved this without their expertise.

VP REGULATORY AFFAIRS, EUROPEAN MEDICAL DEVICE MANUFACTURER

LET'S TALK

## Ready to Map Your Device's Route to Market?

Share your device and target markets, and a RABT Global specialist will map the fastest, most cost-effective route to approval. No commitment, no pressure.

[Get a Free Regulatory Assessment](#)

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