# EU Medical Device Regulations

## Lack of Certification Resources, Exorbitant Fees, and Slow Standards-Harmonization Impede U.S.-E.U. Trade


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## U.S. is the Largest MedTech Exporter to the EU

The United States has the world's largest MedTech industry and the EU is its largest export market[1]. The EU alone represented nearly 40 percent ($21.6 billion) of U.S. MedTech exports in 2018. Moreover, during April 2009–May 2017, the trading bloc captured the second-largest share of foreign direct investment (FDI) from the U.S. medical device sector[1]. The latest iteration of the European Union Medical Device Regulation (MDR) entered into effect on 26 of May, 2021. Some 500,000 medical devices in Europe have been forced to recertify under MDR.

The CE mark designating a medical device appropriate for sale at the EU is provided by a "Notified Body" (NB)—a private EU organization that is authorized to audit and inspect manufacturers' facilities and processes to certify that they comply with EU directives and standards. In addition, once a device is placed on the market, the manufacturer is subject to periodic audits to confirm compliance.

Regulatory practices are critical determinants of the overall ability of U.S. and Minnesota companies producing medical devices to sell their goods competitively in EU member states. EU regulations shape market access for Minnesota MedTech producers and influence decisions about marketing and pricing of their products within EU markets. Regulatory procedures that significantly depart from international best practices can restrict trade, become non-trade barriers, and ultimately delay vital treatments for patients[1].

## New EU MDR Regulations, A Challenge for MedTech Exporters

In reaction to a serious medical device incident in the EU nearly a decade ago, led by Germany, an effort to overhaul the EU medical device regulation began. The result has been a series of evermore complex revisions of MDR[2]. Many unaddressed MDR challenges pose bottlenecks to timely EU market access.

**LACK OF NOTIFIED BODIES**: Due to lack of enough EU NB for certification, only 20% of medical devices have been certified with a deadline of May 2024 looming. The deadline had been moved once, and proposals are trying to move it yet again[3]. The situation is no better in Invitro Diagnostics (IVD) Directive regulations. EU's largest MedTech association, MedTech Europe, released a report[4] in 2022 showing draconian measures are "a disincentive against launching medical device innovation in the EU." The certification process of previously certified legacy devices, the simplest of possible cases, takes 13 to 18 months on average. New devices can take even longer.

**DRAMATIC INCREASE IN REGULATION COMPLEXITY**: Regulation is so complex and approval institutions are so overburdened, that year after year extensions of the implementation deadline are issued (now proposed as 2026-2027 and 2028 limited to legacy devices). EU keeps moving the goal post and raising regulatory complexity for MedTech devices.

**MANUFACTURERS ARE WITHDRAWING FROM EU**: Due to these measures, there has been the reported withdrawal of nearly 15,000 medical devices from the EU market leading to complaints by distributors, importers, doctors, clinics, and hospitals as patients no longer have access to life saving devices.

**NOTIFIED BODIES ARE FOR-PROFIT AGENCIES**: While FDA is a federal not-for-profit agency, EU Notified Bodies holding similar regulatory powers over medical devices, are in fact for-profit agencies. They often lack the capacity to cover their existing client base, let alone accept new clients. Supply and demand for such services have led to a dramatic rise in certification costs.

**EXHORBITATNT FEES DRIVING MEDICAL DEVICE MANFACTURERS OUT OF EU**: Notified Body charge certification fees averaging US$100,000 and recently up to $800,000 Euros for 5 year market access[5]. Some small and medium size companies have been asked by NB's to even pre-pay, 1 year prior to their certification audits. It is estimated that the average small and medium size company needs to sell US$1 Million of medical devices per year in the EU to be able to foot the bill for the EU regulatory fees. In contrast, FDA requires registration that an FDA approved medical device is being sold in the U.S. market at an annual cost of $6493 (as of Feb 2023). This exorbitant fee imbalance between U.S. and EU is a major driving force for especially U.S. small and medium size companies to not submit their devices to or withdraw their devices from the EU market.

**EU HAS CREATED A REREGISTRATION CARROUSEL**: An EU medical device certification for sales is valid only for 3-to-5-years even if the device has seen no changes whatsoever in that period. The MDR forces it through a recertification process. The certification process then begins anew and must be repeated with new exorbitant fees paid. In the U.S. market, once a medical device manufacturer receives FDA clearance, certification need not be resubmitted unless there is a change in the medical device.

## Recommendations

Reciprocity and an even playing field are fundamental pillars of U.S.-EU trade. Yet well meaning regulations borne without the infrastructure required to enable trade and burdened with exhorbitant fees are increasingly viewed as a non-tariff barrier. We recommend:

1. ### EU-U.S. Regulatory Reciprocity

   Regulation and best administrative practices backed by science and evidence can drive both patient safety and market access. We recommend assuring that EU and FDA regulations are compared and are on par. Switzerland (a non-EU country using EU Regulations) has found a commonsense solution to this regulatory challenge agreeing to accept either FDA or EU approved devices without further review. The UK is considering a similar approach. Then one option may be to allow the US small and medium companies to be given the opportunity to ship medical devices into the EU with either FDA or EU approval.

2. ### Financial Support as a counterbalance to Exorbitant EU Fees

   To promote U.S. small and medium size companies to export to the EU markets given the exorbitant fee structure, grant or loan funding may be needed to be made available from either state trade agencies and/or federal trade agencies (Department of Commerce or Small Business Administration, Exim Bank, etc.) Without that the innovation powerhouse of small and medium size MedTech companies is seriously jeopardized.

## Summary

Medical devices are a significant part of Minnesota and indeed U.S. economy. Righting the U.S.-EU regulatory imbalance will benefit our exporters and encourages bilateral Minnesota-EU and overburdened U.S.-EU trade. We want all stakeholders to be educated about how these regulations are having a detrimental effect to exporters. An uneven playing field due to lack of notified bodies, exhorbitant fees, or even lack of harmonization in technical standards create barriers to trade. Regulatory reciprocity and an even playing field in U.S.-EU medical device regulation must be restablished for patients to have access to life saving devices.

## References

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