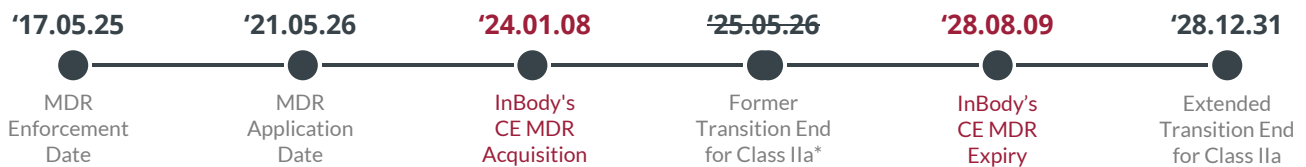


CE Medical Devices Regulation (MDR)

What is CE Medical Devices Regulation (MDR)?

CE MDR stands for Conformité Européenne Medical Devices Regulation, a regulation established by the European Union to ensure the safety, quality, and performance of medical devices. The CE marking signifies that our products comply with the essential requirements outlined in the MDR and can be legally marketed and sold within the European Economic Area (EEA). The Medical Devices Regulation (MDR) was introduced to address shortcomings and enhance the previous regulatory framework, Medical Device Directive (MDD), for medical devices in the European Union.

InBody CE MDR Timeline



*MDR guides device classification for compliance, ensuring conformity and safety. Devices span from Class I (low risk) to Class III (high risk). The Body Composition Analyzer falls under Class IIa, signifying low to medium risk.

What's changed compared to the CE Medical Device Directive (MDD)?

Unlike the Medical Device Directive (MDD), which operated in a directing capacity, the Medical Devices Regulation (MDR) represents a binding regulation. It aims to establish a uniform approach throughout all EU member states, prioritizing consistency in standards, offering clearer definitions, and reducing ambiguity compared to the MDD. The overarching goal of MDR is to enhance patient safety, bolster the reliability of medical devices, and create a cohesive market for these products across the EU.

Why is this important?

Securing CE MDR certification highlights our unwavering dedication to excellence and strict adherence to the highest standards in the medical device industry. Beyond being a testament to our commitment, this achievement strengthens our position in the market, fostering trust among our customers, partners, and regulatory authorities. Attaining CE MDR certification is a significant accomplishment given the demanding regulations, setting our brand apart in the industry. It is worth noting that a considerable number of medical device companies may not have successfully obtained this prestigious certification.