

Unlocking Market Access for Health, Wellness & Beauty Technologies

– Navigating Compliance with Confidence

Laying the Foundation for Compliance and Market Access

Many aesthetic, beauty and wellness products fall under the EU Medical Device Regulation (MDR) – even when they do not have a medical purpose.

For manufacturers of products such as dermal fillers, energy-based devices, and skin penetration technologies, MDR Annex XVI introduces new expectations. These relate to safety, clinical evidence, and how the product is managed across its lifecycle.

At GBA Key2Compliance, we support manufacturers in bringing these products to market – and keeping them there. We combine regulatory, quality, clinical and safety expertise to turn complex requirements into clear, actionable strategies aligned with your product and business objectives.

Products under Annex XVI may include:

- Dermal and mucous membrane fillers
- Devices for skin resurfacing, tattoo removal or fat reduction using light (including IPL), laser, radio-frequency (RF) or mechanical action
- LED and red-light therapy devices, as well as other energy-based technologies (such as RF or electrical stimulation) used for aesthetic or skin treatments
- Contact lenses and eye-colouring devices

Legacy products

Products already on the market often need to be updated to meet MDR Annex XVI requirements. In practice, this often means:

- revisiting the product's classification rationale and regulatory strategy,
- strengthening technical documentation and quality system alignment,
- ensuring appropriate safety documentation (including biocompatibility and toxicology),
- building clinical evidence to support claims, and
- establishing a workable post-market setup to maintain CE marking.

New or evolving products

For new products or product extensions, it pays to build the path to CE marking upfront.

This includes defining intended purpose and claims, setting the regulatory and clinical strategy, establishing the technical documentation, and planning the safety and clinical evidence needed to support your market positioning

GBA Key2Compliance partners with you across the full lifecycle — aligning regulatory, quality, safety and clinical work into a clear, defensible path to market that supports both compliance and commercial success



Clinical Development and Evidence for Health, Wellness & Beauty Technologies under MDR

With the right foundation in place, generating the clinical evidence to support your claims becomes the next critical step toward market access.

At GBA Key2Compliance, our MedTech-focused Contract Research Organisation (CRO) provides end-to-end clinical development support for products under MDR Annex XVI.

We help you generate the clinical evidence needed to support your claims, demonstrate safety and performance, and enable CE marking and market access.

Our services include:

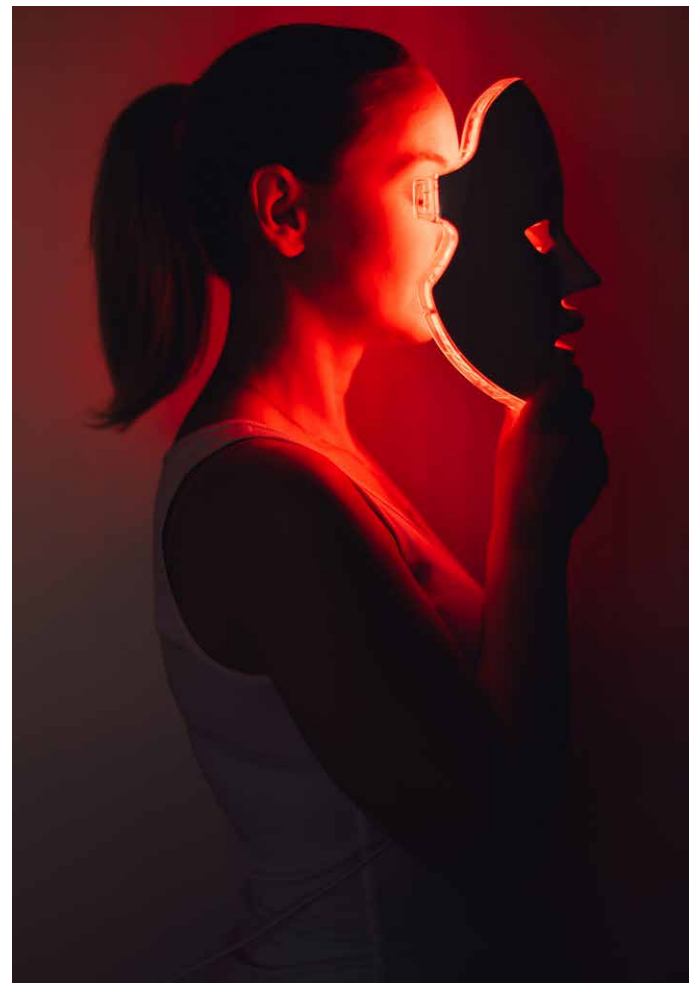
- **Clinical Strategy & Planning** – We analyse your intended purpose and claims, assess risk classification, and define the level of clinical evidence required. This includes clinical evaluation, state-of-the-art (SOTA) development, and GAP assessments — providing a clear, tailored plan for next steps.
- **Clinical Investigations** – When required, we design and manage clinical investigations in accordance with ISO 14155 (Good Clinical Practice) and MDR. This includes study design, documentation, site feasibility and selection, monitoring, data management, and reporting.
- **Flexible, Client-Focused Execution** – We are not a testing clinic. Unlike cosmetic testing facilities, we do not operate our own laboratories or clinics. Each study is built around your product's intended purpose and target population. We identify and qualify the most suitable investigational sites – whether hospitals, dermatology clinics, or specialized centres – based on study design and feasibility needs.

You gain a dedicated project lead and access to our in-house experts in:

- Clinical project management
- Biostatistics
- Safety and data management
- Monitoring
- Medical writing

Our goal is to help you build a scalable and sustainable clinical strategy that supports both market access and ongoing compliance.

Whether you are classifying a new product or strengthening evidence for existing claims, we help you move forward with clarity — reducing risk, avoiding delays, and ensuring a smoother path to market and beyond



Ensuring Product Safety and Compliance



Together with clinical evidence, biological safety forms a core part of the overall evidence required to support your product and claims.

For products under MDR Annex XVI, demonstrating safety is a fundamental requirement for CE marking and continued market access. This includes a structured approach to biological safety, toxicological risk, and material evaluation.

At GBA Key2Compliance, our Biological Safety experts provide scientifically robust assessments that are aligned with your clinical strategy — helping you build a coherent and defensible evidence package that supports both regulatory expectations and commercial success.

Our services include:

- **Biological evaluation (biocompatibility assessment):** Performing and documenting biological evaluations in accordance with the ISO 10993 series, FDA guidance requirements, and other applicable regulatory requirements. This includes the preparation of a comprehensive Biological Evaluation Plan (BEP) and Biological Evaluation Report (BER) to demonstrate the biocompatibility and safety of your product.
- **Toxicological risk assessment:** Perform toxicological risk assessments in accordance with

the principles outlined in the ISO 10993-17, considering the identification and evaluation of chemicals that may be present in the finished medical device or released during use. The toxicological risk assessment contributes to the overall biological evaluation and supports compliance with applicable regulatory requirements, including the ISO 10993 series, FDA expectations, and other relevant frameworks.

- **Testing coordination:** Assisting in coordinating chemical and biological testing with accredited laboratories that operate in compliance with Good Laboratory Practice (GLP). Testing is planned in accordance with the ISO 10993-series, FDA guidance, and other applicable standards and regulatory frameworks.

By partnering with GBA Key2Compliance, you receive reliable guidance to manage product safety, maintain regulatory compliance, and protect consumers and your brand.

Our team combines expertise in both medical device and cosmetic frameworks, ensuring that safety assessments are aligned with your product type, intended purpose, and market positioning. From material selection to final documentation, we help you build a safety foundation that supports both compliance and commercial success.

Why work with GBA Key2Compliance



Working with GBA Key2Compliance means more than meeting regulatory requirements. It means building a clear, structured path from development to market - and beyond - where regulatory, clinical strategy and biological safety are brought together to support your product and its claims throughout its lifecycle.

By combining our expertise with your unique product insight, we create a clear and aligned way forward — reducing risk, avoiding unnecessary work, and ensuring your product stands up to scrutiny over time.

What it means in practice:

- A clear and aligned path forward – not fragmented activities
- Reduced risks of delays, rework, or regulatory pushback
- Efficient use of studies and testing, focusing on what is needed, no more, no less
- Documentation that tells a coherent and convincing story

GBA Key2Compliance is part of the GBA Group, providing access to an international network of experts and laboratories. This enables efficient support across markets, with local insight and cross-border regulatory experience when needed.

Our consultants are ready to work closely with your team, providing hands-on support and guidance at every step of the journey.

Get in touch to discuss your CE compliance needs:

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