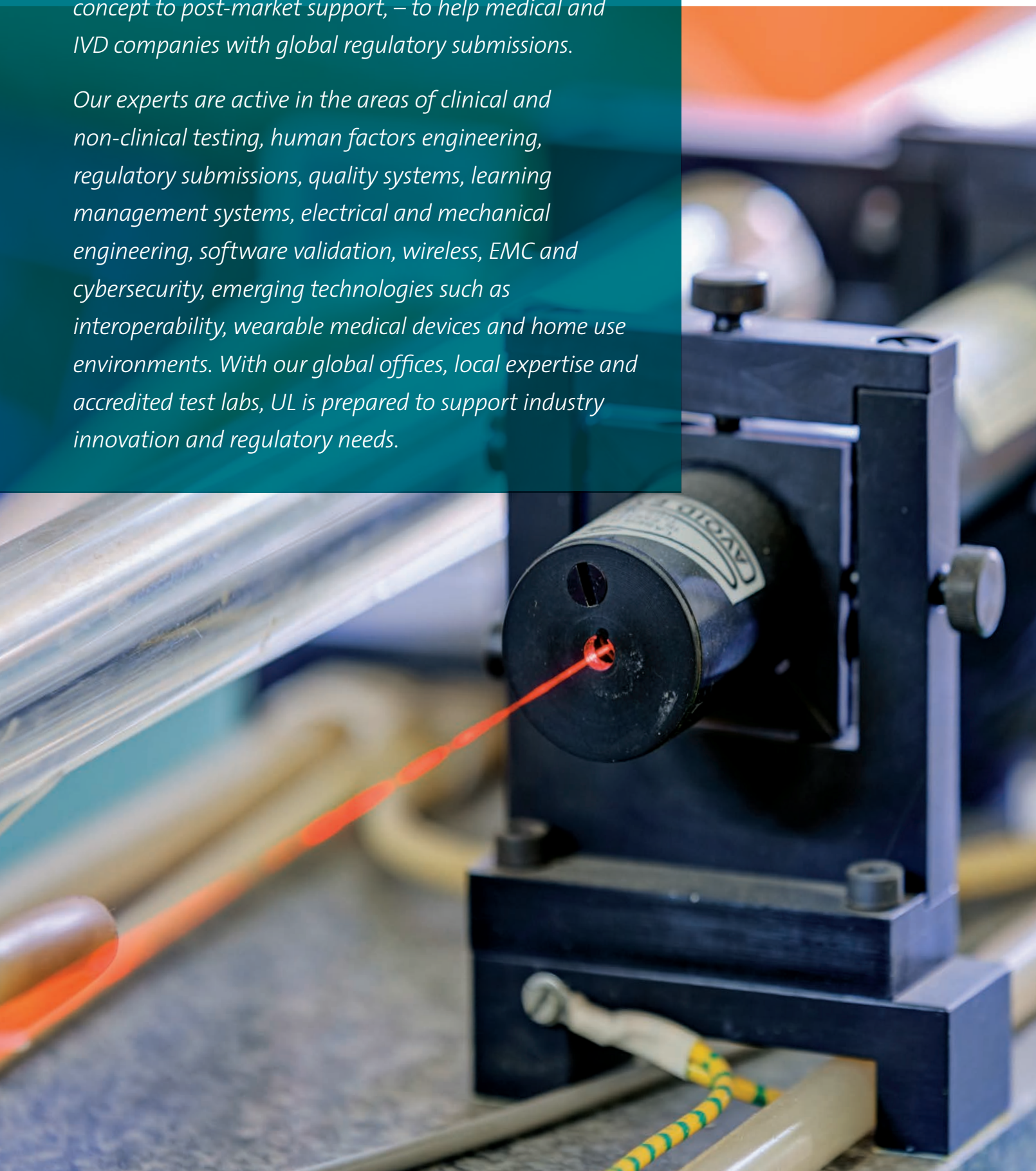
SAFETY REQUIREMENT COMPLIANCE FOR LASERS

IN MEDICAL AND BEAUTY CARE APPLICATIONS

Building off UL's history of more than 120 years of safety science, UL's Health Sciences division provides comprehensive services – from advisory at product concept to post-market support, – to help medical and IVD companies with global regulatory submissions.

Our experts are active in the areas of clinical and non-clinical testing, human factors engineering, regulatory submissions, quality systems, learning management systems, electrical and mechanical engineering, software validation, wireless, EMC and cybersecurity, emerging technologies such as interoperability, wearable medical devices and home use environments. With our global offices, local expertise and accredited test labs, UL is prepared to support industry innovation and regulatory needs.



International Safety Requirements for Medical and Beauty Care Laser Devices

Laser Radiation

A laser can provide many technological benefits to a product but also adds some additional concerns for safety. Laser radiation can be hazardous to the eyes or skin under certain circumstances.

The primary purpose of two base laser standards — **FDA/CDRH 21CFR** in the United States and **IEC 60825-1** outside the United States — is to make sure a product has appropriate safeguards to protect those who use, maintain and service that product.

Some beauty care products that utilize lasers are considered medical devices, but there are many that fall outside the scope. These devices must still comply with the the regulations with respect to laser safety.

U.S. FDA Requirements

U.S. FDA's Center for Devices and Radiological Health (CDRH) regulates laser products marketed, sold, or imported into the United States. Medical device and beauty care device manufacturers that incorporate lasers into products must ensure that their products comply with the **FDA/CDRH 21CFR** regulations.

Compliance with the regulations usually involves:

- Laser power/energy measurements
- Determining the laser classification (how hazardous the radiation is) typically ranging from Class I (least hazardous) to Class IV (most hazardous)
- Manufacturers can rely on CDRH Laser Notice 50, which allows the IEC laser designations of numerals 1-4 instead of Roman Numerals I-IV, and the CDRH will accept IEC generated test data as a basis of the product report submitted to the CDRH
- Ensuring the product complies with the applicable performance requirements (for example: labeling, construction features, user manual statements, etc.)
- Generation of the appropriate CDRH report to send to the CDRH

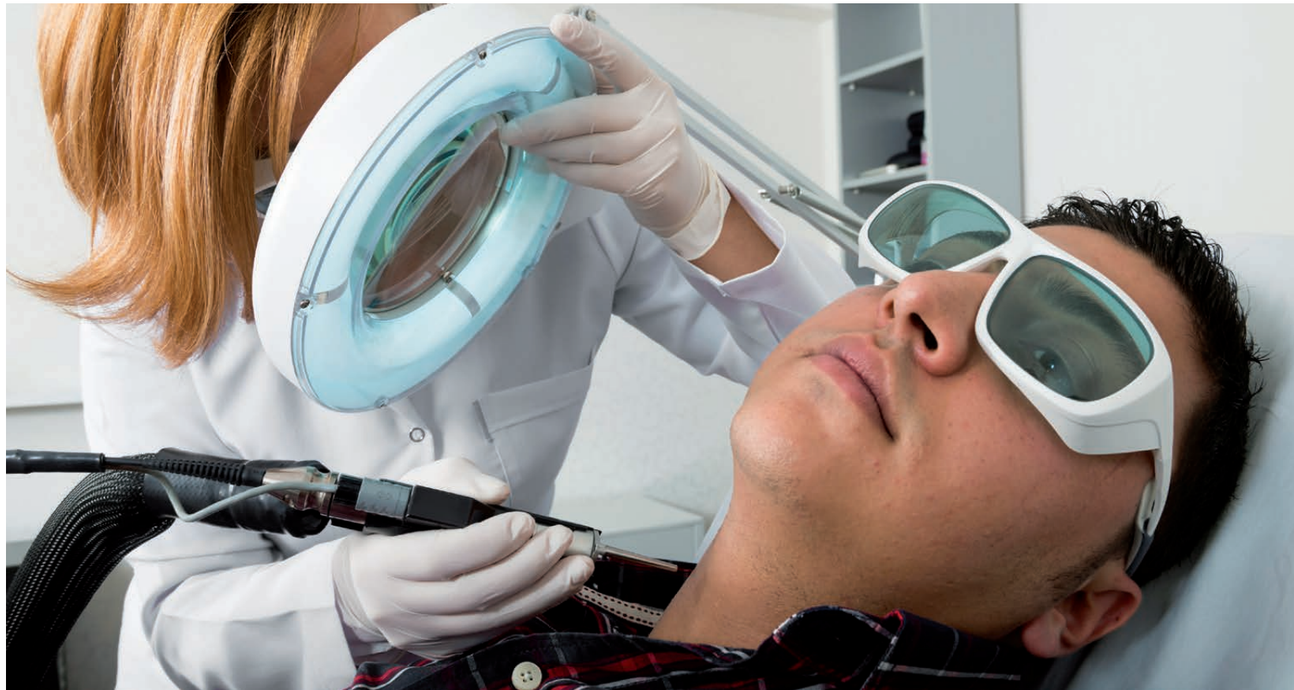
Note that the end product standard may also have specific requirements for lasers and/or refer to recognized laser-specific standards.

FDA Laser requirements for medical products

The FDA/CDRH states laser requirements for medical products in **21CFR Part 1040.11** and also recognizes the particular standard, **IEC 60601-2-22** for medical laser equipment (see IEC Section) via CDRH Laser Notice 50.

IEC Requirements

- **IEC 60825-1**
  "Safety of laser products – Part 1: Equipment classification and requirements"
- **IEC 60601-2-22**
  "Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment" – for Class 3B and Class 4 Medical Laser Products.
- **IEC 80601-2-58**
  "Medical electrical equipment – Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery"
- **IEC 15004-2**
  "Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection"
- **IEC 15752**
  "Ophthalmic instruments – Endoilluminators – Fundamental requirements and test methods for optical radiation safety"
- **IEC FDIS 60335-2-113**
  "Household and similar electrical appliances – Safety – Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating laser and intense light sources"
- **IEC 60335-2-27**
  "Household and similar electrical appliances – Safety – Part 2-27: Particular requirements for appliances for skin exposure to optical radiation"



☑ Regulatory Strategy

Whether you only need help understanding the regulations for the countries in which you seek to market your product, or are looking for a more full-service solution, UL experts can provide everything from market intelligence to working side by side with your team to determine timing and location of market entry, market feasibility, requirements and clinical and non-clinical test plans.

☑ Human Factors Engineering (HFE)

HFE experts can help improve your medical and beauty care product's use-safety and usability. UL's HFE experts can help you evaluate whether users can interact with your device safely and effectively and understand laser-related labeling and precautionary statements. UL can also support the design of the product's user interface, Instructions for Use, and on-product labeling, taking advantage of their extensive knowledge of human factors and user interface design and evaluation.

☑ Non-Clinical Testing

If your product comes into contact with the body or is handheld, UL can help you assess the risk of the device causing irritation or other biocompatibility issues and develop and conduct the appropriate tests.

☑ EMC

UL's first class EMC test labs and network of EMC partners mean that testing and troubleshooting can be conducted near your facility. UL EMC experts can help you identify areas of non-conformity and work with you on suggested fixes.

☑ Regulatory Submission

Having UL technical experts prepare and submit the regulatory documentation on your behalf can save you time and rework. Our global team can also interact in the same time zone and language as the regulatory body, reducing delays and interpretative errors.

☑ Gap Analysis

UL technical experts can review your laser technology products to make sure the regulatory and safety requirements have been met for the region you are selling to.

How UL helps manufacturers of medical and beauty care products that incorporate lasers

UL's full-service laser laboratories can test products to laser safety requirements and provide the needed report format to meet U.S. FDA/CDRH and/or IEC laser safety standards.

☑ Software Validation

Many devices are programmable and run automatically based on the software. UL software experts can help you reduce risks associated with software malfunction by validating your software to recognized standards.

☑ Full Laser Testing Service

UL has full service laser testing laboratories where all types of laser products are tested to both CDRH and IEC laser safety requirements. This full laser testing service can result in a complete CDRH report ready to file with the FDA, or an IEC 60825-1 CB Test Report with CB Certificate.

☑ Electrical and Mechanical Safety

You can come to UL for testing with or without certification, based on your timing and needs and where you are in the development cycle.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=1040.11
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm

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For more information on UL's services to support medical devices and beauty care products with global market access,
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