

SYNRAD Laser Compliance 101

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Introduction/Background

Laser compliance includes both disposal and regulatory information. For additional information please visit our website.

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I. Purpose

This laser compliance white paper outlines the general compliance and applicable regulations. CDRH (Center for Devices and Radiological Health), FCC (Federal Communication Commission) and European Union compliance is located in the laser safety white-paper located on our website.

II. Scope

This laser compliance document includes US and EU regulation information. See the Laser Safety 101 white-paper located on our website.

III. Compliance Overview

SYNRAD lasers are designed, tested, and certified to comply with certain United States (U.S.) and European Union (EU) regulations. These regulations impose product performance requirements related to electromagnetic compatibility (EMC) and product safety characteristics for industrial, scientific, and medical (ISM) equipment. The specific provisions to which SYNRAD must comply per product are identified in the Declaration of Conformity. Note that compliance to CDRH, FCC, and EU requirements depends in part on the laser version selected—Keyswitch or OEM.

In the U.S., laser safety requirements are governed by the Center for Devices and Radiological Health (CDRH) under the auspices of the U.S. Food and Drug Administration (FDA) while radiated emission standards fall under the jurisdiction of the U.S. Federal Communications Commission (FCC). Outside the U.S., laser safety and emissions are governed by European Union (EU) Directives and Standards.

In the matter of EU and U.S. compliant laser products, and SYNRAD, assumes no responsibility for the compliance of the system into which the product is integrated, other than to supply and/or recommend laser components that are CE marked for compliance with applicable European Union Directives.

Because OEM laser products are intended for incorporation as components in a laser processing system, they do not meet all of the Standards for complete laser processing systems as specified by 21 CFR, Part 1040 or Z136.1-2007, Safe Use of Lasers. Subchapter J without additional safeguards. In the U.S., the Buyer of these OEM laser components is solely responsible for the assurance that the laser processing system sold to an end user complies with all laser safety requirements before the actual sale of the system.

U.S. Requirements

Center for Devices and Radiological Health (CDRH) requirements

See product specific features incorporated into the design to comply with CDRH requirements are integrated as panel controls or indicators, internal circuit elements, or input/output signal interfaces. Specifically, these features include a lase and laser ready indicators, remote interlock for power on/off, a laser aperture shutter switch, and a five-second delay between power on and lasing. Incorporation of certain features is dependent on the laser version (Keyswitch or OEM). See Operation Manual for Class 4 safety features available on SYNRAD lasers, the type and description of the feature, and if the feature is required by CDRH regulations.

OEM models

SYNRAD OEM lasers are OEM products intended for incorporation as components in laser processing systems. As supplied by SYNRAD, these lasers do not meet the requirements of 21 CFR, or EN 60825-1 without additional safeguards.

Under CDRH regulations, the Buyer must submit a report to the CDRH prior to shipping the system. In jurisdictions outside the U.S., it is the sole responsibility of the Buyer of these OEM components to ensure that they meet all applicable local laser safety requirements. In cases where the Buyer is also the end-user of the OEM laser product, the Buyer/end-user must integrate the laser so that it complies with all applicable laser safety standards as set forth herein.

European Union Directives state that "OEM laser products which are sold to other manufacturers for use as components of any system for sub-sequent sale are not subject to this Standard, since the final product will itself be subject to the Standard." This means that Buyers of OEM laser components are solely responsible for the assurance that the laser processing system sold to an end-user complies with all laser safety requirements before the actual sale of the system.

Note that when an OEM laser component is incorporated into another device or system, the entire machinery installation may be required to conform to EN 60825-1; EN 60204-1:2006, Safety of Machinery; the Machinery Directive, EN 2006/42/EC; and/or any other applicable Standards and in cases where the system is being imported into the U.S., it must also comply with CDRH regulations.

Disposal

This product contains components that are considered hazardous industrial waste. If a situation occurs where the laser is rendered non-functional and cannot be repaired, it may be returned to SYNRAD® who, for a fee, will ensure adequate disassembly, recycling and/or disposal of the product.

Federal Communications Commission (FCC) Requirements

The United States Communication Act of 1934 vested the Federal Communications Commission (FCC) with the authority to regulate equipment that emits electromagnetic radiation in the radio frequency spectrum. The purpose of the Communication Act is to prevent harmful electromagnetic interference (EMI) from affecting authorized radio communication services. The FCC regulations that govern industrial, scientific, and medical (ISM) equipment are fully described in 47 CFR, Part 18, Subpart C.

SYNRAD lasers have been tested and found to comply by demonstrating performance characteristics that have met or exceeded the requirements of 47 CFR, Part 18, Radiated and Conducted Emissions.

FCC information to the user Interference Potential

In our testing, SYNRAD, has not discovered any significant electrical interference traceable to our lasers.

System Maintenance

Ensure that all exterior covers are properly fastened in position.

Measures to Correct Interference

If you suspect that your laser interferes with other equipment, take the following steps to minimize this interference:

1. Use shielded cables to and from the equipment that is experiencing interference problems.
2. Ensure that the laser is properly grounded to the same electrical potential as the equipment or system it is connected to.

Note: The following FCC information to the user is provided to comply with the requirements of 47 CFR, Part 18, Section 213.

FCC caution to the user

The Federal Communications Commission warns the user that changes or modifications of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

European Union (EU) Requirements

RoHS compliance

SYNRAD lasers meet the requirements of the European Parliament and Council Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment that establishes maximum concentration values for certain hazardous substances in electrical and electronic equipment.

Laser safety standards

Under the Low Voltage Directive, 2006/95/EC, the European Norm (EN) document EN 60825- 1:2007 was developed to provide laser safety guidance and includes clauses on Engineering Specifications, Labeling, Other Informational Requirements, Additional Requirements for Specific Laser Products, Classification, and Determination of the Accessible Emission Level. To develop a risk assessment plan/laser safety program for users, see IEC/TR 60825-14:2004 that includes clauses on Administrative Policies, Laser Radiation Hazards, Determining the MPE, Associated Hazards, Evaluating Risk, Control Measures, Maintenance of Safe Operation, Incident Reporting and Accident Investigation, and Medical Surveillance.

Electromagnetic interference standards

The European Union's Electromagnetic Compatibility (EMC) Directive, 2014/30/EU, is the Directive developed to address electromagnetic interference (EMI) issues in electronic equipment. In particular, the Directive calls out European Norm (EN) documents that define the emission and immunity standards for specific product categories. For SYNRAD[®] lasers, EN 61000-6-4 defines radiated and conducted RF emission limits while EN 61000-6-2 defines immunity requirements for industrial environments.

SYNRAD lasers have demonstrated performance characteristics that have met or exceeded the requirements of EMC Directive 2014/30/EU. See the declaration of conformity for specific details.