MILITARY EXEMPTION AUTHORIZATION (MEA) #XXXXXXX

EXEMPTION NOTIFICATION IDENTIFIER CODE# ABBBBBBCCCCCCDDDDDDEEE

SFTE AU ARH

MEMORANDUM FOR ABC Lasers, Incorporated

 ATTN:

 9 Akira Way

 Londonderry, NH 03053

SUBJECT: AUTHORIZATION TO USE MILITARY EXEMPTION FOR THE XYZ LASER (ARCRONYM IF APPLICABLE)

1. In accordance with Food and Drug Administration (FDA) Exemption No. 76EL-01DoD the following electronic product, being manufactured under contract DAAB08-03-C-H006 is exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations (CFR), Title 21, Chapter 1, Subchapter J, Parts 1040.10 and 1040.11 in order to meet military operational requirements. The issuance signature activity granting this authorization shall maintain inventory of all lasers systems covered by this exemption letter, or property chain for any of these laser systems transferred to another DoD activity.

2. Any modification to this laser product (including material components, physical design, or laser output characteristics), or deviation from the scope defined in the table below require the manufacturer to obtain a new exemption authorization letter.

3. The FDA Laser Notice 52 states that a manufacturer violates Federal law if it delivers a laser system not in compliance with the FDA standard to the DoD unless it first receives a written authorization by the applicable DoD authority to apply the exemption discussed herein. Further, it states that an appropriate DoD laser safety representative must evaluate all military exempt laser products to determine compliance with relevant military and/or Federal requirements. Finally, it requires that the manufacturer maintain evidence of this authorization for use of the military exemption.

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| --- | --- |
| **Parameter** | **Description** |
| **Contract #** | DAAB08-03-C-H006 |
| **Product Name** | XYZ Laser (ARCRONYM IF APPLICABLE)) |
| **Model #** |  |
| **Serial #(s)** |  |
| **Lot #(s)** |  |
| **DoD Service(s)** | US Army |
| **Org./Unit** |  |
| **Quantity** |  |
| **Delivery Dates** |  |
| **Other Limits to Authorization** |  |

4. Although the use of the military exemption has been authorized, the system design must still adhere to the requirements of Military Standard 1425A (MIL-STD-1425A), Safety Design Requirements for Military Lasers and Associated Support Equipment, 30 August 1991, or by special approval by the applicable military laser safety authority. The military exemption requires that the laser system only deviate from those Federal design requirements necessary for the military application for which it was designed. In addition to any other labeling requirements, all systems using the military exemption are required to have a label permanently affixed to the device housing with the information provided below (or alternate wording if approved by the applicable DoD Component laser safety authority):

**CAUTION**

**This electronic product has been exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, under exemption No. 76EL-01DoD issued on July 26, 1976. Use this product only with adequate protective devices or procedures. Do not sell or transfer outside the DoD.**

5. For systems delivered for operational or fielding use, the manufacturer must identify all variations from the design requirements of 21 CFR 1040, complete with justification for each deviation. For systems delivered for other purposes (e.g. testing or evaluation), such information should be provided, as practicable.

The following FDA radiation safety performance standards cannot be met due to military operational requirements:

Deviations from 21 CFR 1040 with justifications are:

Protective Housing

Safety Interlocks

 Remote Interlock Connector

 Key Control

 Emission Indicator

 Beam Attenuator

 Location of Control

 Viewing Optics

 Scanning Safeguard

 Manual Reset Mechanism

 Labeling Requirements

 User Information

 Modification of a Certified Product

6. Each applicable DoD Component may issue additional or alternate requirements and recommendations prior to system approval for procurement or use. Inasmuch, this authorization is not intended to constitute final approval for procurement or use of the systems for which it describes. For further information, please contact the applicable DoD Component's laser safety authority.

7. We are enclosing a copy of the DA Form 4995-R, Laser Exemption from Federal Standards, for your records.

8. If there are any questions, my point of contact is LTC John Q. Doe, (353) 466-7899, john.q.doe@us.army.mil, Product Manager, Aviation, Armed Reconnaissance Helicopter, Attn: SFTE AU ARH, Building 5681, Redstone Arsenal, AL 35898‑5000.

Encl (01) Sincerely,

 John Doe

 Contracting Officer

 PM Aviation

CF: (w/encl)

PM Aviation (SFTE AU ARH)

USAPHC (Prov) (MCHB-TS-OLO/Mr. Rodney Wood)

EXEMPTION STATEMENT

ABC Lasers, Incorporated

9 Akira Way

Londonderry, NH 03053

PEO Aviation, ARH Project Office

5300 Martin Road

Redstone Arsenal, AL 35898-5000

The XYZ Infrared Laser Rangefinder Target Designator (ILRFTD), produced under Contract DAAB08-03-C-H006, is exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No. 76EL-01DOD, issued on July 28, 1976.

This exemption is required in order to allow the ILRFTD to be procured by the U.S. Army for Combat (Combat, Combat training, and/or Classified for reasons of National security) operational requirements. The ILRFTD is unable to comply with all of the requirements of the Federal Performance Standard for Laser Products issued by the FDA, CDRH, in Title 21, CFR, Subchapter J, Parts 1040.10 and 1040.11. The ILRFTD will incorporate all of the design requirements for exempted lasers as required in MIL-STD-1425A, Safety Design Requirements for Military Lasers and Associated Support Equipment. The ILRFTD is unable to comply with the following performance, labeling, and/or informational requirements of 21 CFR 1040. For each requirement that cannot be met, provide rationale for noncompliance. For further information about each requirement see the appropriate paragraph (example (f)(2) from 21 CFR 1040.

(f)(4) Key control: Hinder to mission. Possible safety problem in aircraft cockpit areas

(f)(5) Laser radiation emission indicator: Emission indicator near laser exit aperture would compromise aircraft and crew

(f)(6) Beam attenuator: As an aircraft mounted laser, a beam attenuator would hinder mission

(g)(3) Labeling Requirements, Class IV designations, and warnings: camouflage colors may be required to reduce system vulnerability to enemy

DATE

20 September 2006

**TO:** *(IncludeZIP Code)*

LASERTYPE

NUMBER OF LASERS *(Optional)*

MANUFACTURER

CONTRACT NUMBER

NATIONAL STOCK NUMBER *(if known)*

REMARKS

**DA FORM 4995-R, OCT 1981**

APDPEv1.00

In accordance with an interagency agreement between DOD and HEW, 29 July 1976, the following electronic product(s)

are exempted from FDA radiation safety performance standards prescribed in the Code of Federal Regulations,

Title 21, Chapter 1, Subchapter J, pursuant to Exemption No. 76 EL-01 DOD, issued 26 July 1976.

**FROM:** *(IncludeZIP Code)*

AN/AAS-35A, XYZ Infrared Laser Rangefinder Target Designator (ILRFTD)

 ABC Lasers, Incorporated

DAAB08-03-C-H006

For use of this form, see AR 385-9; the proponent agency is DCSPER.

**LASER EXEMPTION FROM FEDERAL STANDARDS**

**Serializing Military Exemption Notification Letters**

Henceforth, military Exemption Notification Letters (ENL) are required to contain a unique 22 character Exemption Notification Identifier Code (ENIC). The following defines the format required for these codes:

ABBBBBBCCCCCCDDDDDDEEE, where:

A Notification Type (either "P" for provisional or "F" for fielded) Provisional ENLs are limited to prototype, demonstration, or test systems. Provisional ENLs are required to have an expiration date

BBBBBB Date ENL is issued (YYMMDD).

CCCCCC Date ENL expires (YYMMDD). If the ENL does not have an expiration date, this should be "000000". After this date, the manufacturer is no longer permitted to deliver laser products by reference of this ENL. This has no bearing on the user.

DDDDDD Unit Identification Code (UIC) of person signing the notification letter. The first character of the UIC defines the DOD Service issuing the exemption notification.

EEE Three character unique code (at the discretion of the ENIC). This may be the organizational code, favorite lottery number, or any other code that verifies that the overall ENIC is truly unique.

For example, if NSWCDD (UIC N00178) issued a ENIC for a laser system on March 18th, 2012 that is valid for three years and will be used for testing purposes only, the ENIC could be:

 ENIC: P120318150318N00178G73

In this example, the ENIC issuer decided to use their organization code for the last three characters. If they issued another Exemption Notification on the same day, they would be required to use a different three character code or date the ENL differently.