AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
0008		See Block 14	

6. ISSUED BY CODE SPE2DH

DLA TROOP SUPPORT
MEDICAL SUPPLY CHAIIN FSH
700 ROBBINS AVENUE
PHILADELPHIA PA 19111

7. ADMINISTERED BY *(If other than Item 6)* CODE

8. NAME AND ADDRESS OF CONTRACTOR (*No., street, county, State and ZIP Code)*

CODE FACILITY CODE

(X)

[X] 9A. AMENDMENT OF SOLICITATION NO. SPE2DH21R0002

9B. DATED (*SEE ITEM 11*) 2021 DEC 02

[ ] 10A. MODIFICATION OF CONTRACT/ORDER NO.

10B. DATED *(SEE ITEM 13)*

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers [ ] is extended, [ ] is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*

13. THIS APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
[ ]	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
[ ]	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
[ ]	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
[ ]	D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor [ ] is not, [ ] is required to sign this document and return _____ copies to issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

See Attached Continuation Sheet(s).

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
15B. CONTRACTOR/OFFEROR *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	16C. DATE SIGNED

SECTION C - SPECIFICATIONS/SOW/SOO/ORD

The subject solicitation is hereby amended as follows:

(1) Page 8, reference CAUTION NOTICE, hereby includes Section O:

All Department of Defense (DoD) orders must adhere to either the Defense Health Agency's Cybersecurity/Risk Management Framework (RMF) requirements /or individual Military Service RMF requirements for all offered medical systems/devices that receive, process, store, display, or transmit data to government systems.

To ascertain security compliance with United States Federal Government (USFG), Department of Defense (DoD), and Defense Health Agency (DHA) policies and directives, vendors are required to complete and provide the latest version of the Medical Device and Equipment Risk Assessment (MDERA) CyberLOG questionnaire, upon request by the DoD customer.

*All Medical Systems/Devices are required to meet DoD cybersecurity and National Institute of Standards and Technology (NIST) standards, regardless of network connection type.

Compliance is required for the following procedures/standards:

a. Vendors are required to complete and provide the latest Medical Device and Equipment Risk Assessment (MDERA) CyberLOG questionnaire to a DHA POC (listed in b.), upon request by the DoD customer.

DHA may require more documentation, than The Medical Device and Equipment Risk Assessment (MDERA) CyberLOG questionnaire, to identify medical devices'/systems', and equipment classification:

- Assess and Use (A&U) Certification
- Assess and Incorporate (A&I) Certification
- Assess and Authorize (A&A)
    - Each classification has its own set of Cybersecurity/RMF requirements to obtain approvals

b. Vendors will be responsible for contacting the DHA CyberLog Office (DHA.DETRICK.MED-LOG.MBX. CYBERLOG@MAIL.MIL) or DHA ICS (DHA.DETRICK.PEO-MED-SYS-J-6.MBX.DHA-ICS-CYBER-RMF@HEALTH.MIL), immediately after receiving an order to start the RMF process. *Email correspondence/ submission must include an attachment of the delivery order.

c. Any DoD requirement accepted in ECAT must comply with the latest DHA Cybersecurity/RMF requirements. Vendors must:

- Have a valid approval (A&U, A&I, or A&A), or
- Partake in the RMF approval process to obtain A&U, A&I, or A&A (and subsequent approvals for the life of the equipment).

d. If there is a medical device/system that will not meet the specified DHA Cybersecurity/RMF requirements, the vendor shall reject (kill) that requirement in ECAT and notify both the DoD customer and the DLA Contracting Officer of the issue.

e. Vendors may be required to adhere to site-specific Cybersecurity Requirements, upon request by any DoD customer.

f. By accepting any DoD requirement in ECAT, the vendor also agrees to comply with the site-specific Cybersecurity Requirements.

g. If there is a medical device/system that will not meet the specific individual site-specific requirements, the vendor

CONTINUED ON NEXT PAGE

SECTION C - SPECIFICATIONS/SOW/SOO/ORD (CONTINUED)

shall reject (kill) that requirement in ECAT and notify both the customer and DLA Contracting Officer of the issue.

h. Vendors may offer systems that do not meet DHA Cybersecurity/RMF requirements under their contract solely for purchase by non-DoD customers

(2) All other terms and conditions remain unchanged, in full force or effect.