URGENT PRODUCT NOTIFICATION – EBOLA PPE KITS

4 March 2020

{Addressee Name}
{Addressee Title}
{Company Name}
{Company Address}
{City, ST Zip}

Dear Valued Customer:

The purpose of this letter is to advise you about a product sold after August 1, 2018. According to records, you received one or more of the following Ebola PPE Kits:

SS-EK-LG	Ebola PPE Kit (Large)
SS-EK-MD	Ebola PPE Kit (Medium)
SS-EK-SM	Ebola PPE Kit (Small)
SS-EK-XL	Ebola PPE Kit (XLarge)
SS-EVD12	Ebola PPE (12 Kits)
SS-EVD25	Ebola PPE (25 Kits)

(sample image of a kit)

REASON FOR THE NOTIFICATION

VeriCor's Ebola PPE Kits were designed to meet the CDC Personal Protective Equipment (PPE) Guidelines released on August 1, 2014. In August of 2018, the CDC changed some of its guidance. The CDC no longer recommends just impermeable gowns or coveralls for Ebola PPE. Instead, an ANSI/AAMI PB70 Level 4 isolation gown, or an ASTM F1671 (13.8kPa) coverall was recommended for direct patient care in an Ebola isolation situation. The CDC's National Personal Protective Technology Laboratory (NPPTL) states that open back gowns and surgical gowns do not meet the critical area protection/parameters that isolation gowns do and, therefore, using an open-backed gown or surgical gown in isolation settings may not provide appropriate protection. **Thus, the kit you purchased is not in compliance with current CDC Guidelines for Ebola PPE.**

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER

1. Do not use open back gowns or surgical gowns for PPE in an Ebola disease isolation situation.
2. If a VeriCor Ebola PPE Kit is staged to be used, do not use the kit until the open back gown is replaced with a gown or coverall that meets current guidelines by the CDC.
3. Complete the attached customer/user acknowledgement form and mail/fax back ASAP.

Thank you for your prompt return of the form,

VeriCor Customer Care Team

Enc: Customer/User Acknowledgement Form

URGENT PRODUCT NOTIFICATION – EBOLA PPE MODULE

4 March 2020

{Addressee Name}
{Addressee Title}
{Company Name}
{Company Address}
{City, ST Zip}

Dear Valued Customer:

The purpose of this letter is to advise you about a product sold after August 1, 2018. According to records, you received one or more of the following:

SS-EVD100 Ebola PPE 100 Module

(sample image of module)

REASON FOR THE NOTIFICATION

VeriCor's Ebola PPE 100 Module was designed to meet the CDC Personal Protective Equipment (PPE) Guidelines released on August 1, 2014. In August of 2018, the CDC changed some of its guidance.

Change 1: The CDC no longer recommends just impermeable gowns or coveralls for Ebola PPE. Instead, an ANSI/AAMI PB70 Level 4 isolation gown, or an ASTM F1671 (13.8kPa) coverall was recommended for direct patient care in an Ebola isolation situation. The CDC's National Personal Protective Technology Laboratory (NPPTL) states that open back gowns and surgical gowns do not meet the critical area protection/parameters that isolation gowns do and, therefore, using an open-backed gown or surgical gown in isolation settings may not provide appropriate protection.

Change 2: The CDC no longer recommends a fluid-resistant surgical mask with an attached face shield. Instead, a single-use, NIOSH-certified, fit-tested N95 (or higher) respirator in combination with a single-use surgical hood extending to shoulders and a single-use full-face shield was recommended for direct patient care in an Ebola isolation situation.

Therefore, the module you purchased is not in compliance with the current CDC Guidelines for Ebola PPE.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER

1. Do not use open back gowns or surgical gowns for PPE in an Ebola disease situation.
2. Do not use impermeable surgical masks with or without face shield in an Ebola disease situation.
3. If a VeriCor Ebola PPE 100 Module is staged to be used, do not use the module until:
    - the impermeable gown is replaced with a gown or coverall that meets current guidelines by the CDC.
    - the surgical mask (w/ face shield) is replaced with a NIOSH-certified N95 (or higher) respirator AND single-use full-face shield. (Note: The surgical good extending to shoulders is already in the module.)
4. Complete the attached customer/user acknowledgement form and mail/fax back ASAP.

Thank you for your prompt return of the form,

VeriCor Customer Care Team

Enc: Customer/User Acknowledgement Form

CUSTOMER/USER ACKNOWLEDGEMENT (RETURN REQUIRED)

Please initial one of the following options. By initialing, you are acknowledging the receipt of the Urgent Product Notification and understand its contents.

Regarding the Ebola PPE Kits or Module(s) received:

_____ The product has been passed on to someone else. A copy of the notification and acknowledgment has been passed on to the appropriate person.

_____ The notification is no longer applicable as the product is no longer in existence (destroyed, used, retired, lost, etc.)

_____ The choice has been made NOT to update the product. The product will not be used for Ebola PPE.

_____ The choice has been made to update the product ourself. Until then, the product will not be used for Ebola PPE.

_____ Please contact me in regards to the replacement of the affected products. The product will not be used for Ebola PPE until it is compliant with current CDC Guidelines.

_____ Other: _____

_____

_____

Signature: _____ Date: _____ / _____ / _____

Printed Name: _____ Phone: (_____) _____-_____

Email: _____

Once completed, please, do one of the following:

a) fax this form to 608-399-1740
b) scan and email to info@vericormed.com
c) or mail to: VeriCor, LLC
703 Western Ave
Holmen, WI 54636

Ref: V####