SELF-ASSESSMENT QUESTIONNAIRE

Vetting Nontraditional Suppliers

When faced with widespread shortages of personal protective equipment (PPE), medical devices, or other supplies, healthcare organizations may turn to nontraditional suppliers to replenish much-needed equipment. However, it may be difficult to tell if these suppliers—some of which are new and untested—are legitimate or if their products are safe for patient or staff use. This self-assessment questionnaire can be used to help healthcare organizations vet these nontraditional suppliers.

	Yes	No	N/I*	N/A	Comments
Company Website					
1. Is contact information (e.g., email address, telephone number, physical address) listed on the website?					
2. Does the website appear legitimate? (Red flags include spelling mistakes, contradictory information, and the lack of key information such as company information and privacy policies.)					
Manufacturer Information					
3. Contact the manufacturer to determine answers to the following questions:					
a. How long have you been making this product?					
b. What are the names and contact information for U.S. purchasers of the device models under consideration?					
c. Does this product meet all international standards?					
d. Can you provide current photos of the product?					
e. Can you provide a sample of the product to be evaluated?					
4. Does the manufacturer have a history of making the product under consideration? (This can be checked by conducting an internet search or by checking dates on documentation or instructions for use, if available.)					
5. Is the company accredited (e.g., by the National Institute for Occupational Safety and Health [NIOSH])?					

* N/I: Needs Improvement

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	Yes	No	N/I*	N/A	Comments
6. Has the product under consideration been subjected to formal U.S. Food and Drug Administration (FDA) pre-market review?					
7. For N95 respirators:					
a. Is the manufacturer a NIOSH-approved holder? (This can be confirmed by checking the NIOSH Certified Equipment List.)					
b. Can the manufacturer provide ISO/IEC 17025 accredited laboratory test reports demonstrating the filtration efficiency for the face filtering respirators?					
8. Is the company registered with FDA?					
8.1 For domestic products, does the company have a federal tax ID number?					
9. What are the names of other healthcare organizations that have purchased from the manufacturer/supplier in question, and what was their experience? (This can be determined by obtaining a list of references from the manufacturer or by researching via other means, such as through healthcare provider internet message boards and consultation with other healthcare providers.)					

Product Information

10. Have you reviewed the product's specifications and instructions for use to assess whether it will meet your organization's needs?					
11. Have you carefully examined the delivery terms and buying options?					
11.1 Has legal counsel been consulted to review purchasing contracts to help identify any red flags for untrustworthy suppliers and to ensure that contracting terms meet the organization's needs and provide appropriate solutions in case of a breach?					
12. If the company provides sample product, has it been evaluated for effectiveness and safety requirements? (This can be done either in-house or by consulting with a third party. ECRI can assist with the testing and evaluation of certain devices, including face filtering respirators. For more information, contact supplyguide@ecri.org.)					

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