STERIS
Applied Sterilization Technologies

Evaluation Checklist to Process Energy Containing Devices

This checklist is required to identify and assess the risks associated with ethylene oxide sterilization of products which may include batteries or stored energy. Ethylene oxide is flammable and it is foreseeable that energy containing devices or batteries could cause an explosion during sterilization. The safety of personnel as well as protecting our Customer's products during sterilization is critically important. Please work with your STERIS contact to complete applicable sections of the questionnaire and provide additional information as needed..

Customer and Product Details

Customer		**Contact Name**	
Address		**Telephone No.**	
Product Details *(Please give a brief description of the product name, type, serial or other unique identifier.)*			
Proposed Facility		**Sterilization Line / Chamber Nos.**	
Locations Currently Processed?			

Customer Assessment (Completed by Customer)

Please complete the following questions	**Yes**	**No**	**Not Known**
Does the device store any energy (e.g., batteries, capacitors fitted)?			
Does the device contain a motor, heating device, pump, etc.?			
Is there an On / Off switch on the device?			
Is there a mechanism to isolate the battery or prevent the device turning on automatically, e.g. an isolation tab?			
Can the device activate or is it active during the sterilization process?			
Can the device exceed a known safe level of electrical potential or temperature that could ignite ethylene oxide?			
Are the product specification and relevant design details attached?			
If answered Yes to any of above questions, please provide further details below:			
(Please attach sheets or files as needed to confirm device is safe to process. A third-party assessment should be obtained if sufficient Customer documentation is not available.)			

I certify that the information provided regarding the ability to process the above device safely is correct and that any changes to the product or the above information will immediately be notified in writing to STERIS.

Name (Print) **Company/Position** **Signed** **Date**

STERIS Review(Completed by Processing Plant Manager)	**Yes**	**No**
Is the sterilization cycle validated as a 'safe cycle'?		
Is the information provided adequate to fully assess suitability for EO sterilization?		

Name (Print)	**Position**	**Signature**	**Date**
	Plant / Operations Manager		
	HSE		
	Engineering/Technical		