URGENT MEDICAL DEVICE RECALL LETTER RESPONSE FORM

Reference: Gel Separation, M5071A and M5072A, HS22005R/FSN-2021-CC-EC-012

Instructions: Please complete and return this form promptly to SOS Oxygène inc and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Medical Device Recall Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/Province/Postal Code:_____

Customer Actions:

- Continue using the pads as-is. During use, ensure the majority of the pad surface is covered with gel and apply the pads to the patient. If you notice the gel beginning to separate from the foam backing as you peel, try to prevent the gel from folding onto itself if possible. Do not hesitate to apply the pads to the patient unless the gel has almost completely separated from the backing. In case of trouble, install spare pads if available and continue the rescue. No matter the state of the pads, follow the voice prompts because the AED will step you through the necessary actions.
- Do not try to examine the pads gel prior to patient use. It is not possible to know if your pads are affected by the problem prior to use because the pads are protected by a foil seal. The foil seal on the pads cartridge should be opened only for patient use in an emergency because the pads will quickly dry out if the foil seal is broken.
- Consider storing a spare pads cartridge with your HS1/OnSite/Home AED. A short video showing how to replace the pads cartridge can be found at: www.philips.com/replace-aed-pads-video
- If the problem continues and you do not have a spare pads cartridge, attend to the patient, providing CPR if needed, until Emergency Medical Services Personnel arrive.
- Please pass this notice to all those who need to be aware within your organization or to any organization where HS1/Onsite/Home AED devices or pads cartridges have been transferred, (if appropriate.)
- Keep a copy of this letter with the Instructions for Use/Owner's Manual of your HS1/OnSite/Home AED.

☐ I acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall Letter and confirm that the information from this Letter has been properly passed to those who need to be aware.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD/MM/YYYY): _____

Please return this form by email or fax to info@sosmtl.ca or 514-738-4032