



SMART HEALTHCARE™

FLEMING MEDICAL LTD

Corcanree Business Park
Dock Road
Limerick
V94 K6W4
Ireland

phone +353 (0)61 304 600
fax +353 (0)61 304 606
email info@flemingmedical.ie
www.flemingmedical.ie

FIELD SFETY NOTICE / PRODUCT RECALL LETTER

URGENT PRODUCT RECALL

Product Name: Schiller Defibrillation Pads

Product Code: SHL115 and SHL115/1

Lot No: 180322-0777 and 180206-0775

All Product distributed since 25.04.2019. Product with an expiry date of 22.05.2021 & 06.04.2021

08th May 2019

Dear Pharmacist/Doctor/Customer

We wish to advise you that all in-date batches of Schiller Defibrillation Pads SHL115 and SHL115/1, lot No. 180322-0777 and 180206-0775 respectively are being recalled with immediate effect.

Product Code	Lot #
SHL115	180322-0777
SHL115/1	180206-0775

The reason for the recall is that there have been two complaints regarding malfunction during use of the electrode's material on the Schiller Defibrillation Pads. The electrode material was caught between the rivet and the ring terminal of the electrode cable and this has led to no or only intermittent electrical contact between the electrode and the defibrillator.

Please immediately quarantine any units of Lot# 180322-0777 and 180206-0775 of this product which you have in your possession. Ensure that all users or persons concerned in your organisation are aware of this important notice and please confirm notice in the attached form 'Confirmation Safety Notification'. Please return the completed form to Fleming Medical without delay.

If you have supplied these Lots to any other patient / customer, please send them a copy of this recall letter, requesting that they quarantine and return any unsold quantities of these batches to you.

Fleming Medical are endeavouring to make replacement stock of this product available as soon as possible. It is expected that replacement stock will be provided / made available in the coming week. Until then, this product will be unavailable.

We apologise for any inconvenience this action may cause. Please acknowledge receipt of this notification. Should you have any queries, please contact Fleming Medical at telephone number +353 (0) 61 307 777.

Yours sincerely,

Kate Fleming,

Responsible Person, 061-497749; Mobile: 087 2559216 or Kate@flemingmedical.ie