EDEN INNOVATIONS

Field Safety Notice

Urgent Field Safety Notice - RECALL

DOC Fixed and Mobile
Date: 26/11/2019
Type of action: Recall

Date: 26/11/2019

Attention: Directors of ALMAS Industries Ltd subsidiaries and distributors of DOC

Details on affected devices:

DOC fixed and DOC mobile accessory of Philips HS1 defibrillator

Description of the problem

Since December 31, 2017 the medical device DOC accessory of Philips HS1 defibrillator is not compliant with Standard EN 60601-1 version 2012 that has replaced the version 2006 (version according to which the DOC device has been tested)

Tests according this latest version have not been performed because one of the components of the DOC reached the end of life and the new should be available early 2018, which was not the case.

As an accessory of Philips HS1 Defibrillator, the DOC is never in contact with a patient and therefore there is no risk for patients treated with the defibrillator.
Moreover, this nonconformity has no impact on the functioning of this DOC.

Advise on action to be taken by the distributors

It was decided to recall all products that do not comply with safety standards

All DOC with serial number listed below by country must be recalled and returned to EDEN Innovations:

France	United Kingdom	Germany	Ireland	Switzerland
18090092950117E3	1810009424011A49	18090092850117C5	1811009602011EB5	180690092940117E0
18090092950117E2	1810009424011A57	18090092850117CA	1905010340013138	1901009773012386
18090092950117E5	1810009424011A56	1906010378013212		1901009773012387
18090092950117E4	19010098890125D6	1906010378013211		190100977001237E
1809009327011845	19010098890125D5	1906010378013210		190100977001237F
1809009327011846		190601037801320C		190100977001237A
1809009327011847				18090092940117E1
1809009327011848				
1810009426011A87				
1810009426011A88				
190100981201246C				

1901009812012472				
1901009812012471				
19010098120012470				
190100981201246F				

Transmission of this Field Safety Notice

You must send this FSN to all end users and ensure the withdrawal of the products.
The DOC must be returned to EDEN Innovations to exchange with the new version.

Contact reference person

Julien VERON
Tel: 04 42 24 70 40
mailto:julien.veron@eden-innovations.com

The undersign confirms that this notice has been notified the ANSM (French Health Agency).

ALMAS INDUSTRIES
EDEN INNOVATIONS

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Siret 749 971 719 00028 - APE 7112 B
TVA Intracommunautaire FR72749971719

Urgent Field Safety Notice
Response from the subsidiary / distributor

Please complete and email to : julien.verson@eden-innovations.com

Name of the contact person	
Telephone number	
Email	
Name of Distributor	
Postal Address	

I acknowledge that I have reviewed and understand this Urgent Field Safety Notice and accept the implementation of the recall.

Name:

Signature: