

SRN: NL-MF-000000114
BUDI: 8719326941608BS
Reference: 20250522/ECS

URGENT FIELD SAFETY NOTICE / FIELD SAFETY CORRECTIVE ACTION ID-PADDLE LARGE

FSN/FSCA identity: 2025/05/00696 of 22-May-2025
Affected product: iD-Paddle™ Internal Defibrillation Paddle (Large)
EMDN / GMDN: Z12030585 / 66837
Affected lot numbers: 20160426, 20160429, 20160503, 20160504, 20160505

Smart Clinical Products



22-May-2025

Dear customer,

Issue:

During an external audit, we found that we had not properly reported one of our processes to our Notified Body. The process of confirming our product's sterility through accelerated ageing and subsequently extending the sterility expiry date had not been reviewed and approved by the Notified Body prior to implementation.

Potential Risks:

An accredited laboratory conducted accelerated ageing tests on our devices. The results confirmed that the devices would remain sterile until 5 July 2025. Functionality tests also verified that the devices remained functional following the ageing tests. Based on this evidence, we decided to extend the sterility expiry date of the devices.

Since implementing this process, there have been no reported incidents of devices being non-functional or non-sterile.

Our corrective action:

We are notifying all customers who purchased the iD-Paddle from us from the affected lots with an expiry date that has not yet passed. We request our customers to dispose of any iD-Paddle devices from the affected lots found with their sterile barrier intact.

Customer actions needed:

We kindly request that you:

1. Inspect your own stock and that of your customers.
2. Take a photo of the affected iD-Paddles found in your stock in their pouch.
3. Complete the response form and return it with the photo attached.
4. Dispose of the affected devices. Please ensure they cannot be used again by visibly breaching sterility or cutting the blue cable.

Once we have received your disposal confirmation, the completed response form, we will begin the free-of-charge replacement of the disposed devices.

Time:

Please return the response form by 13-Jun-2025 at the latest.

We are committed to replacing the affected devices with new devices as soon as possible.

In accordance with the MEDDEV Vigilance Guidance document Ref. 2.12-1 and Regulation (EU) 2017/745, we confirm that this FSN/FSCA has been notified to the National Competent Authority in your country.

Best regards,

[Redacted signature]

[Redacted name]
(May 26, 2025 15:35 GMT+2)

[Redacted signature]

[Redacted name]
(May 26, 2025 13:15 GMT+2)



Appendix – response form

I have inspected both my own stock and that of my customer for the iD-Paddle™ Internal Defibrillation Paddle (Large).

- There are no iD-Paddle devices in either my own or my customer's stock with the specified lot numbers.
- There are iD-Paddle devices in my own stock or my customer's stock with the specified lot numbers. A photograph of the iD-Paddles in their closed sterile pouches is attached and below the quantities of iD-Paddle devices disposed of are listed:

Affected lot number	Number of devices disposed of
20160426	
20160429	
20160503	
20160504	
20160505	
Date of disposal	DD-MMM-YYYY

I hereby declare that I have disposed of the above-listed iD-Paddles.

Name:	Function:	Signature:
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Please return your completed response form 13-Jun-25 at the latest to gandr@smartclinicalproducts.com

FSNFSCA Customer letter

Final Audit Report

2025-05-26

Created:	2025-05-26
By:	[REDACTED]
Status:	Signed
Transaction ID:	CBJCHBCAABAkc_evm_k9FxaSWFv3wg2lyCaa1mR67Yz

"FSNFSCA Customer letter" History

-  Document created by [REDACTED]
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-  Document emailed to [REDACTED]
2025-05-26 - 10:53:49 AM GMT
-  Document emailed to [REDACTED]
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2025-05-26 - 10:55:41 AM GMT
-  Document e-signed by [REDACTED]
Signature Date: 2025-05-26 - 11:15:24 AM GMT - Time Source: server
-  Email viewed by [REDACTED]
2025-05-26 - 1:32:56 PM GMT
-  Signer Jan Smale [REDACTED] entered name at signing as [REDACTED]
2025-05-26 - 1:35:50 PM GMT
-  Document e-signed by [REDACTED]
Signature Date: 2025-05-26 - 1:35:52 PM GMT - Time Source: server
-  Agreement completed.
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