FSN Ref: E-FSN-2025001

Easymed Instruments Co., Ltd.

Date:11/11/2025.

Urgent: Field Safety Notice
SunStim, SunStim Plus, SunStim Pro
IMMEDIATE ACTION REQUIRED
1st Notification

For Attention of*:Healthcare professionals and distributors.

Contact details of local representative (name, e-mail, telephone, address etc.) *
EasyMed UK Responsible Person: **Name:** AF PHARMA SERVICE UK LTD **Address:** Suite 140 Temple Chambers 3-7 Temple Avenue, London, EC4Y 0DA England, United Kingdom **EU Authorized Rep.** **Name:** mdi Europa GmbH (SRN: DE-AR-000006218) **Address:** Langenhagener Str. 71, 30855 Langenhagen, Germany

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Easymed Instruments Co., Ltd.

Urgent Field Safety Notice (FSN)
SunStim, SunStim Pro, SunStim Plus
Risk addressed by FSN

1. Information on Affected Devices*

1.1. Device Type(s)*

SunStim™, SunStim™ Plus and SunStim™ Pro Peripheral Nerve Stimulators are each a battery-powered device intended for monitoring the magnitude of neuromuscular block in general anesthesia by delivering an electrical stimulus near a peripheral motor nerve.

1.2. Commercial name(s)

SunStim, SunStim Pro, SunStim Plus

1.3. Unique Device Identifier(s) (UDI-DI)*

8-1053-60: 10889483005835, 8-1053-62: 10889483005842, 8-1053-63: 10889483171127

1.4. Primary clinical purpose of device(s)*

Assessment of neuromuscular block that enables a clinician to precisely monitor the depth of muscle relaxation in a patient during surgery and anesthesia recovery.

1.5. Device Model/Catalogue/part number(s)*

8-1053-60 SunStim Peripheral Nerve Stimulator, 8-1053-62 SunStim Plus Peripheral Nerve Stimulator, 8-1053-63 SunStim Pro Peripheral Nerve Stimulator

1.6. Software version

Not applicable

1.7. Affected serial or lot number range

Item Number	Lot Number
8-1053-60	SS23051
8-1053-60	SS23052
8-1053-60	SS23082
8-1053-60	SS23091
8-1053-60	SS24071
8-1053-60	SS24072
8-1053-60	SS24077
8-1053-60	SS24092
8-1053-60	SS24121
8-1053-62	SP23111
8-1053-62	SP24071
8-1053-62	SP24072
8-1053-62	SP24077
8-1053-63	SR22111
8-1053-63	SR23011
8-1053-63	SR23031
8-1053-63	SR23051
8-1053-63	SR23061
8-1053-63	SR23081
8-1053-63	SR23091
8-1053-63	SR23111

8-1053-63	SR24041	
8-1053-63	SR24071	
8-1053-63	SR24073	
8-1053-63	SR24092	

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	Devices delivered without CE marked labelling (product labelling and IFU) to the UK and EU markets. The EU compliant IFU that contains the CE mark and other fields and symbols required by the UK and EU markets is being attached to this FSN (SunStimINIFURev7). The sections of the EU compliant IFU that were not included on the IFU provided with the product include: Device Description, Environment of Use, Patient Target Group, Intended Users, Necessary User Qualifications, Expected Clinical Benefit, Contraindications, and Incident Reporting. There was one new Warning/Caution added, "The operator of this device must not touch the actual battery and the patient simultaneously".
2.	2. Hazard giving rise to the FSCA*
	The noncompliance was due to a lack of proper information and regulatory symbology on the labelling. The missing CE mark on the labelling and the incompliant IFU may potentially lead to an inappropriate application of the device.
2.	3. Background on Issue
	This is tied to specific lots where the CE mark was not included. This does not impact all lot numbers. AirLife/SunMed is the distributor of these products for EasyMed and adds the CE mark product labelling to the product that ships to locations that require it (EU, UK, and New Zealand were impacted in this case). The labels were omitted for the products in scope of this FSN.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions for Use (IFU)
	☒ Other ☐ None
	The instructions for this FSN are separate by customer type. Below lists the Customer immediate actions:
	For AirLife/SunMed: 1. Review the list of affected products. Please examine your inventory for the mentioned lot(s). 2. Quarantine all affected product in inventory. 3. REWORK or DESTROY devices that are at your distribution centers. For Rework: a. Include the CE mark label and updated IFU provided by EasyMed (Attachment C) 4. Complete Attachment A. Please provide the completed form and the records of rework or destruction to EasyMed.

	5. In addition, if you have further distributed this product, please identify your customers/consignees, and notify them of this FSN. Your notification may be enhanced by including a copy of this removal notification letter. **For Distributors:** 1. Review the list of affected products. Please examine your inventory for the mentioned lot(s). 2. Quarantine all affected product in inventory. 3. DESTROY or REWORK devices that are at your distribution centers. For Rework: a. Include the CE mark label and updated IFU provided by EasyMed (Attachment C) 4. Notify your supplier of the destruction and the product will be replaced with conforming product. 5. Complete Attachment A. Please provide the completed form and the records of rework or destruction to EasyMed. 6. In addition, if you have further distributed this product, please identify your customers/consignees, and notify them of this FSN and provide them with the updated IFU provided by EasyMed (Attachment C). Your notification may be enhanced by including a copy of this removal notification letter. **For End-Users and Healthcare Professionals:** 1. Review the list of affected products. Please examine your inventory for the mentioned lot(s). 2. The updated IFU with the applicable CE mark information is being provided to you with the direct distribution of this FSN notice (Attachment C). 3. Please review the IFU and maintain for your records. 4. Dispose of any of the prior IFU SunStimINIFURev6. 5. Complete Attachment B. 6. In addition, if you have further distributed this product, please identify your customers/consignees, and notify them of this FSN and provide them with the updated IFU provided by EasyMed (Attachment C). Your notification may be enhanced by including a copy of this removal notification letter. 7. If you would like to return the affected products, please contact and send back to your contacted distributor.	
3.	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**2. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None EasyMed has updated the IFU. The updated IFU will be provided with the FSN to impacted customers. See the “Actions to be taken by the User section” for more details.	
3.	3. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
	5. If follow-up FSN expected, what is the further advice expected to relate to:	

4	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Easymed Instruments Co., Ltd.
	b. Address	3/F-6/F, Block A, No.4, Fengxin Road, Fengxiang Industrial District, Daliang, Shunde,Foshan, 528300 Guangdong, China
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Regulatory Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Attachment A: SunStim FSN Response Form (for AirLife/SunMed and Distributors) Attachment B: SunStim FSN Response Form (for Healthcare Professionals/End Users) Attachment C: Updated IFU (SunStimINIFURev7) included with FSN
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

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Immediate Action Requested

Attachment A: SunStim FSN Response Form (for AirLife/SunMed and Distributors)

REF NUMBER	LOT NUMBER	QTY RECEIVED (Eaches)	QTY TO BE REWORKED (Eaches)	QTY TO BE DESTROYED (Eaches)

Please check ALL appropriate boxes.

☐ I have read and understand the instructions provided in the letter sent 11/11/2025.

☐ I have checked my inventory.

- ☐ I do not have any affected products.
- ☐ I am reworking the affected products. (Complete and return evidence of rework)
- ☐ I have destroyed and disposed of the affected product. (Complete and return certificate of destruction)

☐ I have further distributed the affected device and have notified the receiving facility by (**specify date & method of notification**):

_____

Have any adverse events been reported to you regarding the affected product? ☐ Yes ☐ No

If yes, please explain: _____

_____

Contact Name: _____

Title: _____

Facility Name: _____

Address: _____

City/State/Zip Code:_____

Telephone Number:_____Email: _____

PLEASE SEND COMPLETED RESPONSE FORM(S) TO:

E-MAIL TO: <winnie@easymed.com.cn>

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Easymed Instruments Co., Ltd.

Immediate Action Requested

Attachment B: SunStim FSN Response Form (for Healthcare Professionals/End Users)

REF NUMBER	LOT NUMBER	QTY on Hand (Eaches)	QTY TO BE RETURNED (Eaches)

Please check ALL appropriate boxes.

☐ I have read and understand the instructions provided in the letter sent 11/11/2025.
☐ I have read and understand the updated IFU SunStimINIFURev7.
☐ I have checked my inventory.
  ☐ I do not have any affected products.
  ☐ I have destroyed and disposed of the affected IFU (SunStimINIFURev6).
☐ I have further distributed the affected device and have notified the receiving facility by (**specify date & method of notification**):
  _____

Have any adverse events been reported to you regarding the affected product? ☐ Yes ☐ No

If yes, please explain: _____

_____

Contact Name: _____

Title: _____

Facility Name: _____

Address: _____

City/State/Zip Code:_____

Telephone Number:_____Email: _____

PLEASE SEND COMPLETED RESPONSE FORM(S) TO:
E-MAIL TO: <winnie@easymed.com.cn>