Shenzhen Leaflife Technology Ltd.
4F, Bldg.C, JMD Industrial Park, No.39 Qingfeng Blvd., Baolong Industrial Area, Longgang Dist., Shenzhen, China.
Tel: +86-0755-27216609 **Fax**: +86-0755-27215592 **Web.:** www.leaflifetech.com

URGENT FIELD SAFETY NOTICE (FSN)

Commercial Name of the affected product: Artmed Opera Spectrahair 4M (Manufacturer Model: LM-L808A)
FSCA-identifier: FSCA20260409-01
Type of action: Device Recall (Local Destruction)
Date: April 8, 2026
Attention: All Affected Customers and End-Users

1. Details on affected devices:

- **Product Name:** Artmed Opera Spectrahair 4M (Manufactured as Leaflife LM-L808A)
- **Lot / Serial Numbers:** All units distributed in Switzerland in 2024 & 2025 (Refer to attached specific Serial Number list).

2. Description of the problem: Leaflife has identified a labeling and documentation error regarding the LM-L808A devices (locally distributed as Artmed Opera Spectrahair 4M). During a review, it was confirmed that the devices sold in Switzerland actually use LED technology instead of a real laser. Due to a mistake in our internal order review and labeling process, these devices were incorrectly shipped with "Laser Therapy Device" labels and Instructions for Use (IFU).

Please note that the physical hardware of the device operates safely within the parameters of LED technology. This is strictly a documentation and labeling correction.

3. Hazard giving rise to the FSCA: The primary hazard arises from the operator utilizing the device based on incorrect technical assumptions (Laser vs. LED). Operators expecting the rapid clinical endpoints of an 808nm laser might erroneously increase the energy levels (fluence) or treatment duration, which could lead to unintended thermal injuries (e.g., burns, erythema).

4. Actions to be taken by the Importer: To ensure continued safe operation and to eliminate the identified risk, we require your immediate cooperation to collect and securely destroy all affected devices:

- **Step 1: Quarantine & Notify:** All customers and distributors must immediately forward this FSN to all end-users who possess the affected devices, instruct them to cease using the device under "Laser" IFU, and arrange for the return of all affected units to the Swiss distributor.
- **Step 2: Local Destruction:** The Swiss distributor must consolidate all returned units from end-users and securely destroy them locally in accordance with local electronic waste disposal regulations.
- **Step 3: Provide Proof of Destruction:** Following destruction, the distributor must complete and return the attached "Consolidated Reply Form," along with mandatory photographic evidence or a formal Certificate of Destruction for the affected devices,

to Leaflife.

5. Contact Information: For any questions regarding this notice or the device collection and destruction procedure, please contact:

- **Contact Person:**
- **Email:** info@leaflifetech.com
- **Company:** Shenzhen Leaflife Technology Co., Ltd.

We sincerely apologize for any inconvenience this may cause and thank you for your prompt cooperation in maintaining patient safety and regulatory compliance.

Sincerely,

Name/Signature

[redacted]

Regulatory Affairs Manager

Shenzhen Leaflife Technology Co., Ltd.

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CUSTOMER REPLY FORM / FSN ACKNOWLEDGEMENT

Reference: Field Safety Notice - Artmed Opera Spectrahair 4M (LM-L808A) Device Recall & Local Destruction.

To be completed by the Swiss Distributor (on behalf of all End-Users / Clinics):

- ☐ Receipt Confirmed: I acknowledge receipt and understanding of the Field Safety Notice.
- ☐ Devices Collected: I confirm that all affected devices have been successfully collected from the end-users (clinics) and returned to our facility.
- ☐ Devices Destroyed: I confirm that all collected devices have been securely destroyed locally in Switzerland. (Photographic evidence or Certificate of Destruction is attached to this form).

Device Information:

- Facility / Clinic Name: _____
- Device Serial Number(s) destroyed: _____

Confirmation:

I hereby certify that the information provided above is true and that the device recall and local destruction actions have been fully completed in accordance with this Field Safety Notice.

- Name / Signature: _____
- Date (DD/MM/YYYY): _____

IMPORTANT: Please return a scanned copy of this signed form ALONG WITH proof of destruction to: info@leaflifetech.com.

(Note: Commercial arrangements regarding the dispatch of replacement devices will be communicated separately upon receipt of this completed form and destruction proof).

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List of Affected Serial Numbers

No.	Serial Number
1	CY000108O6C0004
2	CY000108O6C0008
3	CY0000108P370001
4	CY0000108P4R0001
5	CY0000108P470001
6	CY0000108P6O0001
7	CY0000108P7T0001
8	CY0000108P8B0001
9	CY0000108P8B0002
10	CY0000108P8K0001
11	CY000108O6C0003
12	CY000108O3C0004
13	CY000010803C0001
14	CY000108O6C0007
15	CY000108O3C0003
16	CY000108O3C0005
17	CY00000108O580001
18	CY000108O6C0005
19	CY000108O6C0002
20	CY000010803C0002