PERIODIC SAFETY UPDATE REPORT (PSUR)

Hyaluronic Acid Dermal Filler

“DermalSoft Plus”

CONFIDENTIAL – INTERNAL REGULATORY DOCUMENT

Document Control

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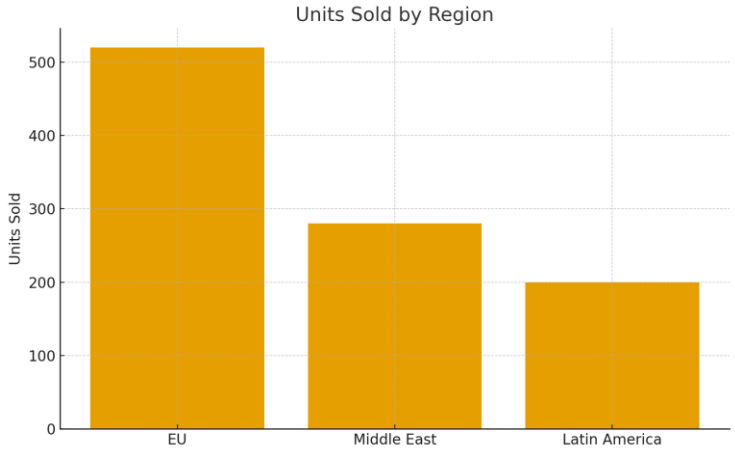
Manufacturer	**ABC Aesthetics Ltd**
Device	HA Dermal Filler — DermalSoft Plus
Intended Purpose	Dermal augmentation, wrinkle correction, volumizing effect
Product Description	Cross-linked hyaluronic acid dermal filler, 24 mg/mL HA, BDDE-stabilized, 1 mL syringe
Risk Class (MDR)	Class III
Reporting Period	01/01/2024 – 31/12/2024

1. Sales & Distribution Data

Below is the updated distribution data with sales visualization:



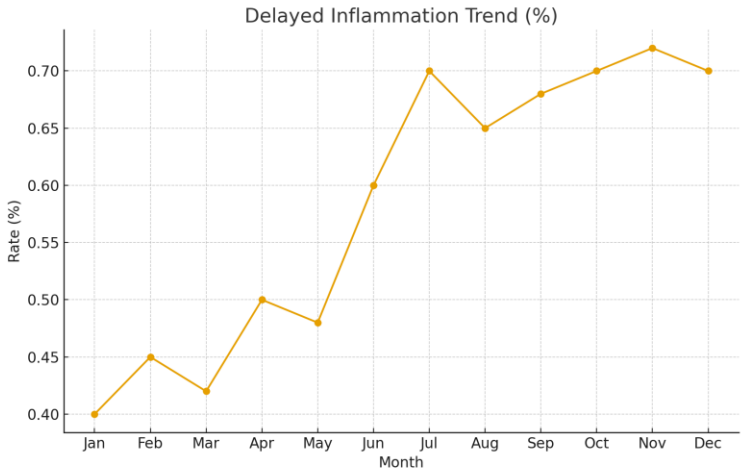
Region	Units Sold	Estimated Patients	AE Reports	AE Rate
EU	520	520	4	0.77%
Middle East	280	280	1	0.36%
Latin America	200	200	2	1.00%

2. Summary of PMS Data

Updated PMS findings:

Source	Findings	Comments
Customer Complaints	18 complaints (0.6%)	Mostly mild early swelling
Delayed Inflammation	0.7% (7/1000 units)	Signal triggered — above threshold 0.5%
Granulomas	0.2% (2 cases)	Within acceptable range
Serious Incidents	0 vascular occlusions	No serious risks identified

2.1 Trend Analysis — Delayed Inflammation



3. PMCF Results Summary

PMCF included passive monitoring and an active observational study.

Active Study Population	612 patients followed 12 months
Early Swelling	5.4% — within expected range
Delayed Reactions	0.7% — exceeded internal threshold
Corrective Measures	CAPA initiated to investigate batch variability

4. Benefit–Risk Determination

Based on PMS and PMCF data, the benefit–risk profile of the DermalSoft Plus filler remains acceptable. Benefits include predictable volumizing effect, high patient satisfaction, and low rate of serious adverse events. The risk level remains in line with known risks of HA fillers, although delayed inflammatory reactions slightly exceeded the acceptable internal threshold (0.7% vs permitted 0.5%). This requires further monitoring.

5. CAPA & Risk Management Update

A CAPA process was initiated to investigate the increase in delayed inflammatory reactions. Preliminary analysis suggests possible dependency on injection technique variability rather than product formulation. No reformulation required at this stage. Risk Management File updated (Revision 2.3).

6. Conclusions

The device continues to meet safety and performance requirements of MDR 2017/745. Annual PSUR is maintained for Class III devices. PMCF activities will be expanded next year to include comparative analysis between multiple practitioner groups and continuous monitoring of geographical AE trends.

Executive Summary

This Executive Summary provides a high-level overview of the safety and performance profile of the DermalSoft Plus hyaluronic acid dermal filler over the 12-month reporting period.

Total Units Sold	1,000
Estimated Patients	1,000
Overall AE Rate	0.7%
Serious Incidents	0
PMCF Study Population	612 patients
Benefit–Risk Conclusion	Positive – Product remains safe & effective

Overall, the benefit–risk ratio remains strongly favorable. No life-threatening or irreversible adverse events were identified. All rates remain within expected ranges for HA dermal fillers.