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Ponte San Nicolò, October 27th, 2025

Field Safety Notice Update
Change to GOT multi medical device labelling

Manufacturer: AL.CHI.MI.A. S.r.l.
FSN Reference No: FSN000473 (related to CLAIM000473)

Table 1. Information on involved medical devices

Medical device	Description	Ref.
GOT multi SF_6	Pure sulfur hexafluoride, repeated-use canister	GOT 007-00, GOT 007-01
GOT multi C_2F_6	Pure hexafluoroethane, repeated-use canister	GOT 008-00, GOT 008-01
GOT multi C_3F_8	Pure octafluoropropane, repeated-use canister	GOT 009-00, GOT 009-01

Dear *Distributor*, Dear *Healthcare Professional*,

AL.CHI.MI.A. S.r.l. is writing to update you on the change regarding the colour of the labelling for GOT multi medical devices, ophthalmic gases intended for long-term intraocular tamponade in vitreoretinal surgery, following the initial field safety notice release by AL.CHI.MI.A. S.r.l. on February13th, 2025.

This notice concerns the following products:

- **GOT multi SF_6**: Ref. GOT 007-00, GOT 007-01;
- **GOT multi C_2F_6**: Ref. GOT 008-00, GOT 008-01;
- **GOT multi C_3F_8**: Ref. GOT 009-00, GOT 009-01.

The purpose of this notice is to provide a progress update on the corrective action about the field issue that occurred, and to raise the user's awareness regarding the correct use of the device by verifying the gas chemical name and formula indicated on products labelling (i.e., the carton and the aluminum canister), and reviewing the IFU provided.
This notice also ensures that all users are informed of the update of labelling of GOT multi medical devices, as consequent corrective action.

Please read carefully the "Important Update" section on page 4 of this FSN update.

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Description of the product

GOT multi SF_6 (Ref. GOT 007-00, GOT 007-01), GOT multi C_2F_6 (Ref. GOT 008-00, GOT 008-01), and GOT multi C_3F_8 (Ref. GOT 009-00, GOT 009-01) are pure sulfur hexafluoride, pure hexafluoroethane, and pure octafluoropropane, respectively. These ophthalmic gases are contained in aluminium canisters and packaged in cardboard cartons.

Each canister contains 75 ml of gas for repeated use. The gas must be diluted with air prior to use to achieve appropriate non-expansile concentrations (i.e., 20% for SF_6, 16% for C_2F_6, and 12% for C_3F_8). The correct dilution ensures that the gas behaves in a non-expansile manner, minimizing potential adverse events.
The choice of gas type depends on the desired tamponade duration (approximately 15 days for SF_6, 30 days for C_2F_6, and 60 days for C_3F_8) according to the surgeon's evaluation of the specific clinical condition to be managed.

Reason for notification

Description of the incident, risk to the patient, and cause

- On September 4th, 2024, a UK hospital reported to AL.CHI.MI.A. S.r.l. that the cartons for GOT multi SF_6 and GOT multi C_3F_8 medical devices were mistakenly exchanged during an ophthalmic surgical procedure, due to similar packaging colours (see **Annex 1** for details).
- The incorrect gas type - thus wrong concentration – was administered, leading to blindness in two (2) patients.
- The incident was due to the user's failure to adequately verify the chemical name and formula of the gas on the packaging, compounded by the similarity in packaging colours.

Post-market safety assessment

- These two (2) incidents are the only reported adverse events involving patients since devices market introduction (i.e., 2007 for GOT multi 00X-00 variants, 2022 for GOT multi 00X-01 variants).
- No similar incidents have been reported since the initial FSN distribution to distributors and end users
- The current device risk profile remains unchanged, supported by post-market analysis and clear labelling of the gas chemical name and formula on both the gas cartons and aluminium canisters.

Action being taken by AL.CHI.MI.A. S.r.l.

As a corrective action to improve the identification of GOT multi medical devices, to further mitigate residual risks of misuse, and strengthen the device safety, and therefore the patient safety, **AL.CHI.MI.A. S.r.l. is updating the labelling of these products**. **Specifically, the colour of the cartons and aluminium canisters will be changed to facilitate safer and clearer gas selection**.

There will be no changes to the intended use of the devices, and they will continue to meet the required safety and performance standards.

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The package label changes are as follows:

- **Device Carton colour update**[1]

Table 2. Colour update of the cardboard boxes

Medical device	Ref.	Current box colour	Updated box colour
GOT multi SF_6	GOT 007-00, GOT 007-01	Orange	Yellow
GOT multi C_2F_6	GOT 008-00, GOT 008-01	Light Orange	Blue
GOT multi C_3F_8	GOT 009-00, GOT 009-01	Dark Orange	Red

This update is intended to aid accurate gas selection by the users as pack differentiation is enhanced.

- **Aluminium canisters label colour update**[2]

The labels on the GOT multi aluminium canisters will match the colours of the cartons as follows:

Table 3. Colour update of the aluminium canisters

Medical device	Ref.	Current canister label	Updated canister label
GOT multi SF_6	GOT 007-00, GOT 007-01	Neutral (aluminium)	Yellow
GOT multi C_2F_6	GOT 008-00, GOT 008-01	Neutral (aluminium)	Blue
GOT multi C_3F_8	GOT 009-00, GOT 009-01	Neutral (aluminium)	Red

This update is intended to allow users to verify that the aluminium canister and carton correspond before using the gas.

Impact of the labelling updates

The new pack designs will feature enhanced visual distinctions, making it easier for users to identify and select the correct gas type, thereby improving patient safety during ophthalmic surgeries.

Timeline for new packaging

The products **GOT 007-00 (SF6)** and **GOT 008-00 (C2F6)** have already had the new pack designs implemented into production.
The remaining products **GOT 007-01, GOT 008-01, GOT 009-00, and GOT 009-01** will be have the new pack designs implemented into production within **Q1 2026**.

[1] *Details of the new pack designs for the GOT multi cardboard boxes (Ref. GOT 00X-00 and GOT 00X-01 variants) as compared to the current ones are depicted in* ***Annex 1****.*

[2] *Details of the new pack designs for the GOT multi aluminium canister labels (Ref. GOT 00X-00 and GOT 00X-01 variants) as compared to the current ones are depicted in* ***Annex 2*** *and* ***Annex 3****.*

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Important Update:

AL.CHI.MI.A. S.r.l. communicated in February 2025 that all new pack designs would be implemented by Q3 2025, however due to a combination of difficulties in the procurement of materials and raw materials, along with delays in outsourcing activities and internal manufacturing processes at AL.CHI.MI.A the implementation of the new pack designs has been delayed for device references **GOT 007-01, GOT 008-01, GOT 009-00** , **GOT 009-01**. As the new design will not be available until Q1 2026, there is a tangible risk of product shortage, which may cause disruption in public healthcare services, including the inability to perform ophthalmic surgical procedures, thus compromising the possibility to improve the patients' clinical conditions; in this regard AL.CHI.MI.A. S.r.l. has informed the Notified Body about the situation.

To avoid this scenario and ensure continuity of care, AL.CHI.MI.A. S.r.l. will continue to supply the previous package design for references GOT 007-01, GOT 008-01, GOT 009-00 and GOT 009-01.

For references GOT 007-00, GOT 008-00, will continue to be supplied with the new design.

In order to safeguard patient safety and ensure proper awareness of end users, this updated Field Safety Notice **will be physically provided with each product box for the old pack design (GOT 007-01, GOT 008-01, GOT 009-00 and GOT 009-01)**, so that it can be read immediately by qualified medical personnel prior to use.

Furthermore, this updated FSN will be shared with all distributors, who are required to cascade this information.

The updated expected resolution date for the corrective action implementation concerning references **GOT 007-01, GOT 008-01**, **GOT 009-00** and **GOT 009-01** is within **Q1 2026**.

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Advice on action to be taken by the distributor

- Maintain this notice in your records until AL.CHI.MI.A. S.r.l. has implemented the planned corrective action.

- Transmit this notice to all users (healthcare professionals) of the GOT multi medical devices and any other person within your organization who needs to be informed.

- Complete the attached **Customer response form** (**Annex 4**) and return it to AL.CHI.MI.A. S.r.l. (vigilance@alchimiasrl.com) within ten (10) days after receipt, as confirmation of receipt and understanding of this notice.

- Reassure users that they may continue using the GOT multi medical devices in the current labelling configuration, as no changes are made to the intended use of the devices, until the corrective action detailed is implemented.

Advice on action to be taken by the user (healthcare professional)

To mitigate risks associated with this issue, instruct the user to take the following actions:

- Read in full this FSN accompanying the product with legacy design (**GOT 007-01, GOT 008-01, GOT 009-00** and **GOT 009-01**) before use.

- Before each surgical procedure, verify the correct gas type, by double-checking the gas chemical name and formula on both the carton and aluminium canister.

- Consult the IFU provided with the product for the correct dilution of the gas, as per the specific clinical need.

- Instruct all relevant personnel who handle these products about the importance of verifying the labelling.

By following these actions, users will help minimize the risk of misuse or incorrect gas administration during surgeries, thus ensuring patient safety.

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Further Information

AL.CHI.MI.A. S.r.l. will notify the National Competent Authority of the field corrective action accordingly.

AL.CHI.MI.A. S.r.l. sincerely apologizes for any inconvenience this may cause and appreciates your understanding and cooperation in ensuring the continued safety, quality, and effectiveness of our products.

Please share this notice with all relevant personnel within your organization to ensure awareness and compliance with this safety recommendation.

For further details or to request additional information regarding this communication, please contact:
vigilance@alchimiasrl.com.

Thank you for your attention.

Yours Sincerely,

Bruno CHERMETTE
President and CEO

Bruno Chermtette
AL.CHI.MI.A. S.r.l.
Person Responsible for Regulatory Compliance

List of attachments

- **Annex 1**: *Layouts of the new and current GOT multi cardboard boxes, ref. GOT 00X-00 and GOT 00X-01 variants*
- **Annex 2**: *Layouts of the new and current GOT multi aluminium canisters labels, ref. GOT 00X-00 variants*
- **Annex 3**: *Layouts of the new and current GOT multi aluminium canisters labels, ref. GOT 00X-01 variants*
- **Annex 4**: *Customer response form*

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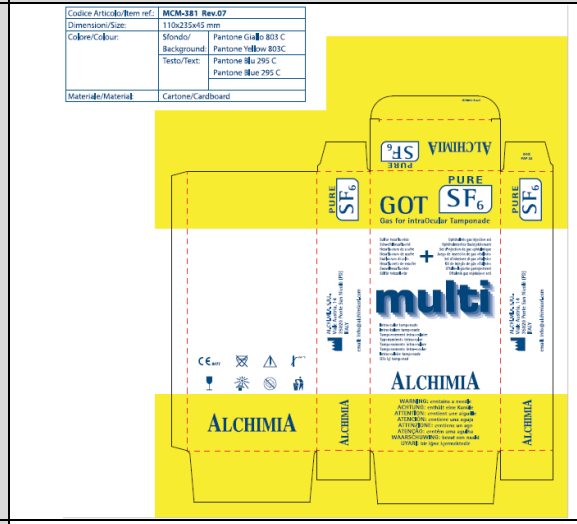
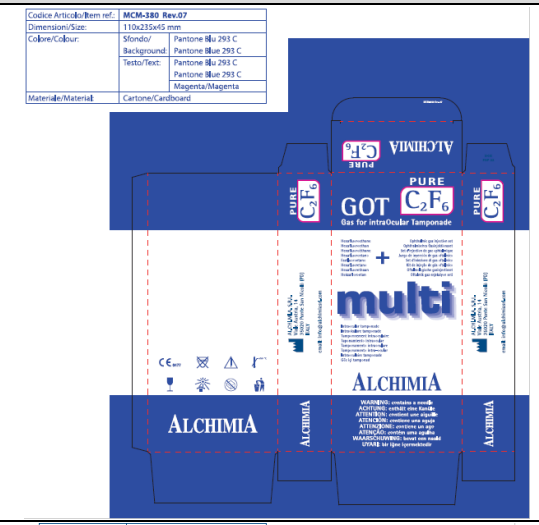
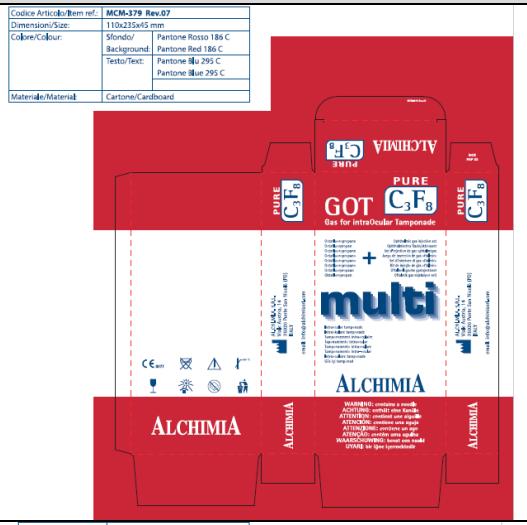
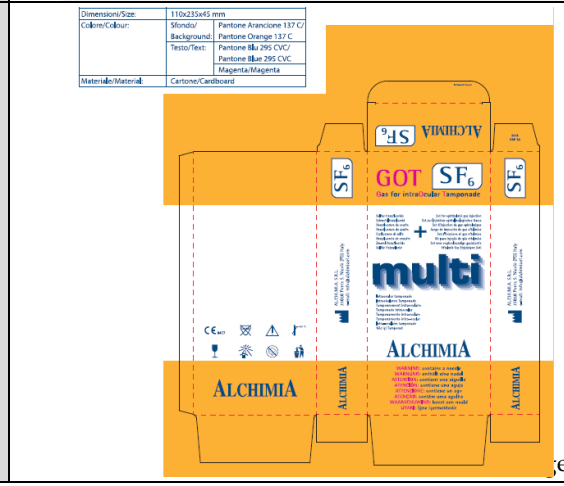
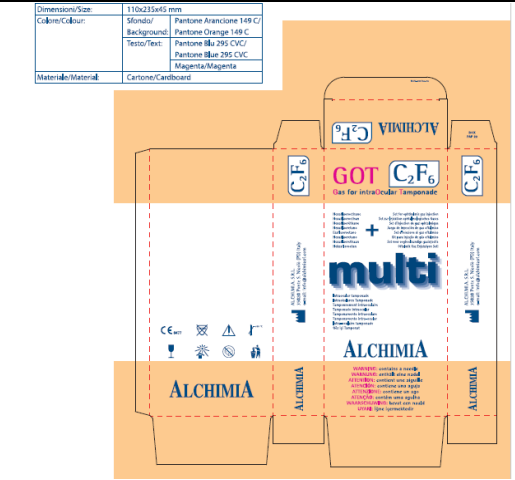
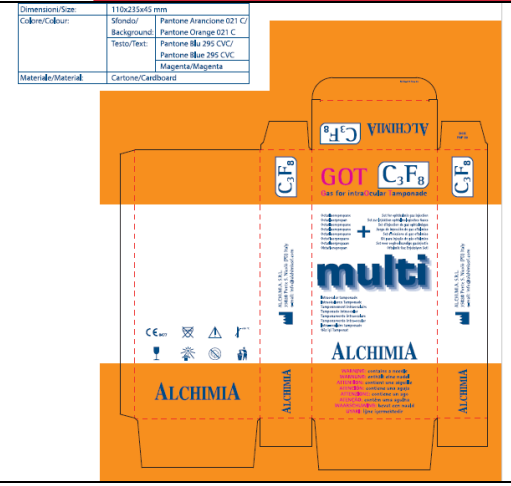
Annex 1: *Layouts of the new (on top) and current (on bottom) GOT multi cartons, ref. GOT 00X-00 and GOT 00X-01 variants.*

	GOT multi SF_6 cardboard box (Ref. GOT 007-00, GOT 007-01)	GOT multi C_2F_6 cardboard box (Ref. GOT 008-00, GOT 008-01)	GOT multi C_3F_8 cardboard box (Ref. GOT 009-00, GOT 009-01)
New labelling			
Current labelling			

Annex 2: *Layouts of the new (on top) and current (on bottom) GOT multi aluminium canisters labels, ref. GOT 00X-00 variants.*

	GOT multi SF_6 canister label (Ref. GOT 007-00)	GOT multi C_2F_6 canister label (Ref. GOT 008-00)	GOT multi C_3F_8 canister label (Ref. GOT 009-00)
New labelling			
Current labelling			

Annex 3: *Layouts of the new (on top) and current (on bottom) GOT multi aluminium canisters labels, ref. GOT 00X-01 variants.*

	GOT multi SF_6 canister label (Ref. GOT 007-01)	GOT multi C_2F_6 canister label (Ref. GOT 008-01)	GOT multi C_3F_8 canister label (Ref. GOT 009-01)
New labelling			
Current labelling			

Dear *Customer*,
please fill this report form in full block capitals according to the notice forwarded to your attention and return it to vigilance@alchimiasrl.com. Thank you.

Annex 4 - Customer response form

Subject: Change to GOT multi medical device labelling
Field Safety Notice Update

Customer details	
Organization name	
Address	
ZIP code and City	
Country	
Telephone number	
Email	

Customer action(s) undertaken	
☐	I hereby acknowledge receipt of this letter and that I have read and understood its content.
☐	The notice has been brought to the attention of all users of GOT multi medical devices and anyone else within our organization who needs to be informed.

Date	Name (in block capitals)	Signature	Stamp

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