Rev 1: September 2018 FSN Ref:	FSCA Ref: Company Name/Logo

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

Device Commercial Name: Blood Glucose Meter / Blood Glucose Test Strip
Risk addressed by FSN: Regulatory non-conformity relating to IVDD classification and conformity assessment route; EU-wide recall/withdrawal process initiated.

Date	2026.05.20
Device Commercial Name	Blood Glucose Meter / Blood Glucose Test Strip
For Attention of*	EU importers, distributors, retailers, healthcare professionals, and any organisation where the affected devices have been transferred. Where affected devices have been supplied to patients / lay users, this notice should also be communicated through the relevant distribution channels.
Contact details of local representative*	SUNGO Europe B.V. Confidential business information

1. Information on Affected Devices*

No.	Field	Filled information
1.1	**Device Type(s)***	In vitro diagnostic blood glucose measuring system consisting of blood glucose meters and associated blood glucose test strips.
1.2	**Commercial name(s)**	Blood Glucose Meter Blood Glucose Test Strip
1.3	**Unique Device Identifier(s) (UDI-DI)**	Not available / not assigned under IVDD. The affected devices were declared under Directive 98/79/EC, and no UDI-DI was assigned at the time of placing on the EU market.
1.4	**Primary clinical purpose of device(s)***	Measurement of glucose concentration in blood to support blood glucose monitoring. The products are under reassessment as blood glucose self-testing / patient self-monitoring devices for the EU market.
1.5	**Device Model/Catalogue/part number(s)***	Blood Glucose Meter: BGM-T1, BGM-T2 Blood Glucose Test Strip: TS-25, TS-50, TS-100
1.6	**Software version**	
1.7	**Affected serial or lot number range**	To be confirmed through retrospective reconciliation of sales, procurement, logistics and customer stock records. Until final reconciliation is completed, all units of the listed models placed on or made available on the EU market are treated as provisionally affected.
1.8	**Associated devices**	Blood Glucose Meter and Blood Glucose Test Strip used together within the same blood glucose monitoring system.

2. Reason for Field Safety Corrective Action (FSCA)*

No.	Field	Filled information
2.1	**Description of the product problem***	Regulatory non-conformity relating to the IVDD classification and conformity assessment route. The existing EU Declarations of Conformity classify the affected devices as "Others (IVDD)" under Directive 98/79/EC and indicate conformity assessment under Annex III without notified body involvement. Competent authorities have concluded that the devices should be treated as blood glucose self-testing devices under IVDD Annex II List B requiring notified body involvement.
2.2	**Hazard giving rise to the FSCA***	Continued sale, distribution or use of devices placed on the EU market without the required notified body conformity assessment for the relevant device category may expose patients / lay users to indirect risk. At the date of this draft, the manufacturer has not identified evidence of a product quality, safety or performance defect. The FSCA is initiated to control the market risk arising from the regulatory non-

		conformity.
2.3	**Probability of problem arising**	The regulatory non-conformity potentially applies to all affected devices of the listed models placed on or made available on the EU market under the existing IVDD declaration. The probability of patient harm is under Health Hazard Evaluation. No confirmed adverse event trend has been identified at the date of this draft.
2.4	**Predicted risk to patient/users**	To be completed following Health Hazard Evaluation. Interim assessment: potential indirect patient risk may arise if patients / lay users rely on results from devices that have not followed the required EU conformity assessment route for self-testing blood glucose devices. The risk is mitigated by immediate stop sale, quarantine, return/removal actions, downstream notification and use of alternative appropriately CE-marked blood glucose monitoring products where needed.
2.5	**Further information to help characterise the problem**	V1.0
2.6	**Background on Issue**	The manufacturer and authorised representative received communications from the Belgian Federal Agency for Medicines and Health Products (FAGG/AFMPS) and the Dutch Health and Youth Care Inspectorate (IGJ) regarding IVDD classification, notified body involvement and EU market status of the affected devices. The manufacturer has initiated an EU-wide recall/withdrawal process, stopped further placing on the EU market, and started retrospective reconciliation of sales, stock and downstream distribution records.
2.7	**Other information relevant to FSCA**	The final affected lot/serial number range and distribution scope are being confirmed through available sales, logistics, procurement and customer stock records. Further updates will be provided to the competent authorities and customers as information becomes available.

3. Type of Action to mitigate the risk*

No.	Field	Filled information
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 Details: Immediately identify all affected devices in stock or under your control. Stop any further sale, distribution, transfer, supply or making available of the affected devices. Quarantine all remaining stock. Forward this notice to all downstream customers and to any organisation to which the affected devices have been transferred. Provide the requested stock and distribution information to the manufacturer and/or the authorised representative. Return arrangements will be communicated separately. Where patients / lay users are in possession of affected devices, blood glucose monitoring should not be discontinued without appropriate alternative monitoring arrangements. Patients / lay users should use an alternative appropriately CE-marked device and consult a healthcare professional if results are unexpected or if there are concerns about treatment decisions
3.2	**By when should the action be completed?**	Stop sale, quarantine and notification: immediately upon receipt of this notice. Customer reply form: within 5 working days of receipt or by [insert date]. Return/removal completion: to be confirmed following reconciliation of stock and downstream distribution.
3.3	**Particular considerations for / Is follow-up of patients or review of patients previous results recommended?**	Patients / lay users and organisations involved in distribution of the affected devices. No routine retrospective review of previous results is recommended at this stage, unless a patient, lay user or healthcare professional has concerns, unexpected results, or a clinical reason for review. This statement is subject to completion of the Health Hazard Evaluation.
3.4	**Is customer Reply Required?***	Yes. A customer reply / effectiveness check form should be attached and returned within the requested deadline.
3.5	**Action Being Taken by the Manufacturer**	☑ Product Removal ☐On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☑ Other ☑ None Details: The manufacturer has initiated an EU-wide recall/withdrawal process due to regulatory non-conformity relating to the IVDD classification and conformity assessment route. The manufacturer has stopped further placing on the EU market, instructed EU customers to stop sale and quarantine stock, requested

		retrospective sales, distribution and stock data, and initiated CAPA. As part of the CAPA and future regulatory compliance plan, the manufacturer has initiated the IVDR Class C conformity assessment process with notified body involvement. The IVDR contract with the notified body has been signed, and the application form has been communicated and completed. The manufacturer is waiting for the notified body system/portal to open within this month in order to upload the technical documentation. These IVDR conformity assessment activities are part of the corrective and preventive action plan and are not used to support continued placing on the EU market before completion of the required conformity assessment.
3.6	**By when should the action be completed?**	Initiated immediately. Final completion date to be confirmed following customer stock reconciliation and return/removal arrangements.
3.7	**Is the FSN required to be communicated to the patient / lay user?**	Yes, where affected devices have been supplied to patients / lay users. The manufacturer is currently confirming downstream distribution with EU distributors. Patient / lay user communication will be issued where end-user distribution is confirmed.
3.8	**If yes, has manufacturer provided additional information suitable for the patient/lay user?**	To be prepared / issued where end-user distribution is confirmed.

4. General Information*

No.	Field	Filled 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?***	Yes
4.5	**If follow-up FSN expected, what is the further advice expected to relate to?**	Final affected lot/serial number range, final distribution scope, return/removal logistics, customer reply results, effectiveness check outcome, and patient / lay user communication where applicable.
4.6	**Anticipated timescale for follow-up FSN**	
4.7	**Manufacturer information**	Website address: Confidential business information
4.8	**The Competent (Regulatory) Authority of your country has been informed about this communication to customers.***	FAGG/AFMPS and IGJ are aware of this matter. Further national competent authorities will be informed as required based on final distribution scope.
4.9	**List of attachments/appendices**	Customer Reply Form / Effectiveness Check Form; Product identification list; EU Declaration of Conformity; sales and stock reconciliation template; CAPA plan; patient / lay user information letter where applicable.
4.10	**Name/Signature**	Personal data

	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. Please transfer this notice to other organisations on which this action has an impact. 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