AURUM HEALTHCARE SDN BHD

URGENT FIELD SAFETY NOTICE

Aurum Healthcare Tubing Systems
Date of issue: 16th July 2018
Type of action: Recall

To the attention of: Distributor and Users of Aurum Healthcare Tubing Systems

List of affected products:	22-1042-00, 22-1042-01, 22-1042-02, 22-1042-08, 22-1042-11, 22-1042-18, 22-1042-21, 22-1042-25.
Lot Numbers:	All lot numbers listed in the Annex to this notice

Dear Customer,

We are sending you the following communication concerning some tubing lines manufactured by Aurum Healthcare and distributed in Switzerland and Austria.

Reason for this recall:

Some tubing systems of Aurum Healthcare were put on the market without a valid CE certificate authorizing the CE mark to be affixed to the device and device commercialization.

A CE mark may only be affixed once a conformity assessment procedure has been completed and approved to confirm the compliance of the products with the essential quality and safety requirements described in Annex I of the Medical Devices Directive EC/93/42. Due to unforeseen circumstances, the final approval was not received on due time and the labeled units were shipped to the market.

Although **no potential quality or safety issue** linked to the use of these products has been identified, those devices do not meet the labeling requirements and should not have been released to the market.

As a remedy to the situation, Aurum Healthcare immediately decided to recall the affected devices from the market pending final approval and issue of the new CE certificate.

Actions to be taken by the distributor:

You'll find attached the list of affected devices shipped to your facility.
Please make sure to identify those products in your warehouse and quarantine them.

1. Identify the users where the devices were shipped and send them this Field Safety Notice with the attached Customer Return Form.
2. Collect the unused product and Customer Return Form with the acknowledgement of receipt from the user and inventory status.
3. Send the signed return form to the point of data collection mentioned in this notice. Update the reconciliation table accordingly.
4. Quarantine the returned products in your warehouse until further instructions are received from Aurum as to the return of the affected goods.

Actions to be taken by the user:

Your local Distributor has provided you with this recall notice including a list of all the catalogue number (Part No) and Lot No that has to be recalled.

Please check whether you have any unused product(s) of the concerned batches at your facility.
If so, do not use the product(s) and contact you distributor to organize the return.
Please confirm receipt of this notice by completing the attached customer return form with details of the lot numbers and quantities of any affected units at your facility. A nil return is also necessary.

Transmission of this Field Safety Notice

Please distribute this notice to any potential user at your facility or to any organisation to which the products were supplied.

Please make sure that all the final users are made aware of the recall by signing the Customer Return Form in annex.

Aurum Healthcare intends to complete the recall within 04 weeks.

Contact point

Should you have any questions about this notice, please contact us at the below address You may also obtain direct assistance by emailing to Mr Rajan (QA/RA Manager) at rajan@aurumhealthcare.com.

Address : No 16, Jalan Laman Setia 7/1,
Taman Laman Setia, Setia Business Park
81550 Gelang Patah, Johor, Malaysia
Tel: + 607-553 9487 / 9
Fax: + 607-553 9485

The undersigned confirms that the relevant National Competent Authorities have been notified of this recall.

Thank You

R Rajan S Ramakrishnan
Quality Assurance Manager
Aurum Healthcare Sdn Bhd

AURUM HEALTHCARE SDN BHD

Urgent Recall Notice

Product Range: Aurum Healthcare Tubing Systems

Customer Return Form

Product Return Address:

Austria — **SMD MedicalTrade GmbH**
Übersiedlungs-Experts-Gasse 5 / 6, 2521 Trumau, Austria

Switzerland — **SMD MedicalTrade AG**
Rheinsichtweg 2, 8274 Tägerwilen, Switzerland

Please complete this Customer Return form and fax or email it back within 5 days to

Contact Person **Ueli Büchi**

Austria	info@smd-medicaltrade.at Tel : +43 676 428 66 67 Fax : + 43 1 253 30 33 65 55	**Switzerland**	info@medicaltrade.ch Tel : +41 71 660 09 14 Fax : +41 71 660 09 15

Facility Information: (stamp)

Facility name:
Address:

Product information: See attached list for devices supplied to your facility

Receipt acknowledgement of this notice:

By signing, you confirm that you have received the Field Safety Notice, dated 16th July 2018 concerning Aurum Healthcare Tubing Systems and have taken note on the information contained within.

- ☐ I confirm that this facility has received this notice and have read the content:
- ☐ I confirm that we have no remaining unused device at our facility
- ☐ I confirm that the following devices are available and quarantined at our facility

Part No	Lot Number(s)	Quantity
22-1042-00		
22-1042-01		
22-1042-02		
22-1042-08		
22-1042-11		
22-1042-18		
22-1042-21		
22-1042-25		

Name: _____ **Signature:** _____
Function: _____
Date: _____ **(dd/mm/yy)** **Contact No. / Email:** _____

List of Affected Products

Part No	Item Description	Lot No
22-1042-00	MRS222, MR-Tube System: 21 Bar/ 305 psi	161251-03
		170800030
		171200013
22-1042-01	Patient Tubing With Non Return Valve, 21 Bar, 25cm	170900029
22-1042-02	Patient Tubing Straight 150cm, 21 Bar, 1-Way Valve	161251-05
		170800031
		170900031
22-1042-08	Pressure Connecting Tube, "Y" 24 Bar, 2 1-Way Valve, 200cm Coiled	161252-01
		170310-12
22-1042-11	Patient Tubing Straight 250cm, 21 Bar, 1-Way Valve	161251-04
		170800032
		180200019
22-1042-18	Coiled Line 21 Bar, 250cm Length	170600006
		170900030
22-1042-21	Coiled Line, 200cm Length, 1 Way Valve 21 Bar	170900028
22-1042-25	Pressure Connecting Tube "Y" 24 Bar, 2 1 Way Valve	170900032
		170800014
		170800033