From,

Head of Quality
QualiMed Innovative Medizinprodukte GmbH
Boschstraße 16, 21423 Winsen, Germany

Urgent Field Safety Notice

Product	Peripheral Vascular Self Expanding Stent System
FSCA-identifier	FSCA2023-02
Type of action	Return to manufacturer

Date: 05/12/2023

Attention (Name of Distributor/customer/end user): Eiemedical Import and Export Medical

Details on affected devices:

Peripheral Vascular Self Expanding Stent System
Refer Lot Numbers mentioned in Appendix I: List of impacted lots

Description of the problem:

We have reason to believe that some lots of our products 'Peripheral Vascular Self Expanding Stent System' (refer Appendix I), may pose a risk to consumers due to an issue with a specific raw material lot used as a component for manufacturing of these lots. During the product testing, it was found that the tip used in these lots can break off/separate during application of the product. While we have not received any reports of injuries related to this issue, we take responsibility for the patient and urge you to stop using the product immediately.

Please note that within these lots, the issue is limited only to tip component and there is no issue with the stent itself. Therefore, there is no need to take any action if the stent has been implanted successfully and catheter is removed successfully without separation/loss of tip.

Advise on action to be taken by the user:

- identifying and quarantining the devices from lot numbers mentioned in Appendix I.
- Notify QualiMed if any product is available for possible return by filling Appendix II and sending it to QualiMed.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations 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.

Contact reference person:

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The undersigned confirms that this notice will be notified to the appropriate Regulatory Agency as per company procedures.

Appendix I: List of impacted lots

Delivery Note Number	Delivery Note-Date	Article Number	Lot Number	Qty
2301356	29.09.2023	261725Q3PA0906012TM	Q464258A	1

Appendix II: Products available for return

Article Number	Lot Number	Quantity	Product available for return? (Yes/No)
261725Q3PA0906012TM	Q464258A	1	

Prepared by: Name-

Designation/Company-

Signature and Date-