
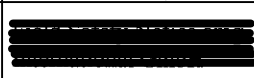


Urgent Field safety Notice		 QualiMed. <small>Innovative Medizinprodukte GmbH</small>
Document: QFB099	Revision: 04	
Document type: QualiMed Formblatt (QFB)	Effective Date: 15.07.2021	


From,

Quality Manager
QualiMed Innovative Medizinprodukte GmbH
 Boschstraße 16, 21423 Winsen, Germany

Urgent Field Safety Notice

Product	Peripheral Vascular Self Expanding Stent System
FSCA-identifier	FSCA2023-01
Type of action	Return to manufacturer

 Date: 28/04/2023

Attention (Name of Distributor/customer/end user): 

Details on affected devices:

Peripheral Vascular Self Expanding Stent System
 Refer Lot Numbers mentioned in Appendix 1: 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 1), may pose a risk to consumers due to an issue with a raw material lot (inner sheath lot 17929-01) used as a component for manufacturing of these lots. During investigation for an internal CAPA (CAPA2022-11-0038), it was found during the product testing (simulated use) that the inner sheath used in these lots can break 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 inner sheath 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.

Advise on action to be taken by the user:

- identifying and quarantining the devices from lot numbers mentioned in Appendix 1.
- Notify QualiMed if any product is available for possible return.

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Transmission of this Field Safety Notice:

This notice needs to be passed on to 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:

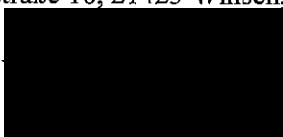


QualiMed Innovative Medizinprodukte GmbH
Boschstraße 16, 21423 Winsen, Germany

Direct

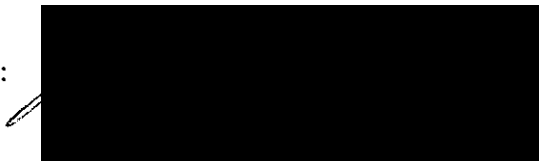
Mob


Mail



The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.


Signature:




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Appendix 1: List of Impacted Lots

Delivery Note	Delivery Note-Date	Article Description	Lot Number	Expiry	qty
2100369	03.03.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x60 mm Stent 80cm Usable Catheter Length	N407216A	12.2023	2
2100032	15.01.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x100 mm Stent 80cm Usable Catheter Length	N406756A	12.2023	1
2100032	15.01.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x100 mm Stent 80cm Usable Catheter Length	N406756B	12.2023	1
2100369	03.03.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x120 mm Stent 80cm Usable Catheter Length	N406757C	12.2023	1
2100032	15.01.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x150 mm Stent 80cm Usable Catheter Length	N406759A	12.2023	1
2100032	15.01.2021	FACILE Peripheral Vascular Self Expanding Stent System 6x150 mm Stent 80cm Usable Catheter Length	N406759B	12.2023	5
2100369	03.03.2021	FACILE Peripheral Vascular Self Expanding Stent System 8x40 mm Stent 80cm Usable Catheter Length	N406760A	01.2024	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 5x20mm Stent 80cm Usable Catheter Length	M402595A	09.2023	2
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 5x40mm Stent 80cm Usable Catheter Length	M402596A	11.2023	2
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 5x60mm Stent 80cm Usable Catheter Length	N402597A	11.2023	2
2200053	24.01.2022	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 6x200mm Stent 120cm Usable Catheter Length	P429108A	11.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 8x80mm Stent 120cm Usable Catheter Length	M402598A	08.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 8x100mm Stent 120cm Usable	M402599A	09.2023	3

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		Catheter Length			
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 9x40mm Stent 80cm Usable Catheter Length	M402601A	09.2023	2
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x40mm Stent 80cm Usable Catheter Length	M402602A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x60mm Stent 80cm Usable Catheter Length	M402603A	09.2023	2
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x80mm Stent 80cm Usable Catheter Length	M402604A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x100mm Stent 80cm Usable Catheter Length	M402605A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x100mm Stent 120cm Usable Catheter Length	M402606A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x120mm Stent 80cm Usable Catheter Length	M402607A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 10x120mm Stent 80cm Usable Catheter Length	M402607B	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 11x40mm Stent 80cm Usable Catheter Length	M402608A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 11x100mm Stent 120cm Usable Catheter Length	M402610A	09.2023	2

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2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 11x120mm Stent 80cm Usable Catheter Length	M402611A	09.2023	1
2100015	13.01.2021	FACILE Pin Pull Peripheral Vascular Self Expanding Stent System 11x120mm Stent 120cm Usable Catheter Length	M402612A	09.2023	1

Informationsblatt		QualiMed <small>A 32 Medical Company</small>
Dokument / Document: QFB211	Revision: 02	Attachment 1
Dokumenttyp / Document type: QualiMed Formblatt (QFB)	Datum des Inkrafttretens / Effective Date: 10.04.2019	

Attachment 1 to FSCA2023-01: List of lots in scope (Sent to German customers)

Article Number	Catalogue Number	Lot Number	Mfg Date	Expiry Date
261666Q3PA050200863	50 APF 20-80	M402595A	10.2020	09.2023
261666Q3PA050400863	50 APF 40-80	M402596A	12.2020	11.2023
261666Q3PA080801263	80 APF 80-120	M402598A	09.2020	08.2023
261666Q3PA081001263	80 APF 100-120	M402599A	10.2020	09.2023
261725Q3PA090400863	90 APF 40-80	M402601A	10.2020	09.2023
261725Q3PA100400863	100 APF 40-80	M402602A	10.2020	09.2023
261725Q3PA100600863	100 APF 60-80	M402603A	10.2020	09.2023
261725Q3PA100800863	100 APF 80-80	M402604A	10.2020	09.2023
261725Q3PA101000863	100 APF 100-80	M402605A	10.2020	09.2023
261725Q3PA101001263	100 APF 100-120	M402606A	10.2020	09.2023
261725Q3PA101200863	100 APF 120-80	M402607A	10.2020	09.2023
261725Q3PA101200863	100 APF 120-80	M402607B	10.2020	09.2023
261725Q3PA110400863	110 APF 40-80	M402608A	10.2020	09.2023
261725Q3PA111001263	110 APF 100-120	M402610A	10.2020	09.2023
261725Q3PA111200863	110 APF 120-80	M402611A	10.2020	09.2023
261725Q3PA111201263	110 APF 120-120	M402612A	10.2020	09.2023
261666Q3PA050600863	50 APF 60-80	N402597A	12.2020	11.2023
261666Q3AA061000862	60 AHS 100-80	N406756A	01.2021	12.2023
261666Q3AA061000862	60 AHS 100-80	N406756B	01.2021	12.2023
261666Q3AA061200862	60 AHS 120-80	N406757C	01.2021	12.2023
261666Q3AA061500862	60 AHS 150-80	N406759A	01.2021	12.2023
261666Q3AA061500862	60 AHS 150-80	N406759B	01.2021	12.2023
261666Q3AA080400862	80 AHS 40-80	N406760A	02.2021	01.2024
261666Q3AA060600862	60 AHS 60-80	N407216A	01.2021	12.2023
261666Q3PA062001263	60 APF 200-120	P429108A	12.2020	11.2023