


XXXXXXXXXX Customer Address and Contact xxxxxxxxxxxxxxxxxxxxxxxx

| Place/Date: **Basel, 19.12.2019** | Reference: **Urgent Field Safety Notice**

## URGENT: Field Safety Notice

Dear Sir or Madam,

On December 19th, Medartis AG has initiated a lot specific product Field Safety Corrective Action (FSCA) for the 2.5 Trilock Screw 14mm, HD7 (A-5750-14/1S).

<b>Product Recall:</b>		2.5 Trilock Screw 14mm, HD7	
<b>Date</b>	19.12.2019		
<b>Part Number</b>	A-5750-14/1S	<b>Lot Number</b>	17169656, 18190766, 19194557, 19200335
<b>FSCA identifier</b>	FSCA-2019-001		
<b>Type of Action</b>	Field Safety Corrective Action: Product Return to supplier (Medartis AG)		
<b>Description of the Problem</b>	<p>Medartis discovered <b>an error on the label</b> of the A-5750.14/1S screws: the mention “<i>not for clinical use</i>” is visible on the label.</p>		
			
	<p>The screw itself <b>does not represent a risk for the patient</b>: it has been manufactured within the specification.</p>		
	<p>The label is incorrect and the error impacts the 4 lots mentioned above.</p>		

<p><b>Advise on Actions to be taken</b></p>	<ul style="list-style-type: none"> <li>➤ Please kindly quarantine and return the affected A-5750.14/1S screws to Medartis.</li> <li>➤ Please kindly fill in and return the attached “Customer Acknowledgement Form” (QF41405). to <a href="mailto:return@medartis.com">return@medartis.com</a></li> <li>➤ Please kindly forward this notification to all potentially affected divisions in-house.</li> <li>➤ Please be aware that the current information sent per email will also be sent per mail to your facility.</li> </ul>
<p><b>Medartis Contact person</b> Kontaktperson</p>	<p>Erwan Nicolle Tel: +41 61 633 36 38 E-Mail: <a href="mailto:return@medartis.com">return@medartis.com</a></p> <p>Medartis AG Hochbergerstrasse 60E 4057 Basel</p>

Swissmedic, our responsible National Authority has been notified on this incident. We kindly apologize for all inconveniences this could cause and remain at your complete disposal for further inquiry.


Kind Regards,

Medartis AG

**Field Safety Corrective Action: 2.5 TriLock Screw 14mm, HD7**

<b>Datum/Date</b>	19.12.19		
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<b>Artikel – Nr./ Part No.</b>	<b>A-5750.14/1S</b>	<b>Lot – Nr./No.</b>	17169656, 18190766, 19194557, 19200335
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<b>Failure Description</b> <i>Fehlerbeschreibung</i>	<p>Medartis discovered <b>an error on the label</b> of the A-5750.14/1S screws: the mention “<i>not for clinical use</i>” is visible on the label.</p> <div style="text-align: center;">  </div> <p>The screw itself <b>does not represent a risk for the patient</b>: it has been manufactured within the specification.</p> <p>The label is incorrect and the error impacts the 4 lots mentioned above.</p>
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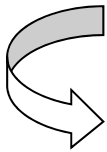
<b>Customer</b> <i>Kunde</i>	XXXXXXXXXXXXXXXXXX
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<b>Anzahl fehlerhafter Produkte beim Kunden</b> <i>Number of affected products at customer</i>	<b>Anzahl</b> <i>quantity</i>	<b>Artikel/Lot</b> <i>Part/LOT</i>	<b>Lieferschein Nr.</b> <i>Delivery Note</i>
	XXX	XXX	XXX
	XXX	XXX	XXX

Für die oben genannten Produkte wurde ein **Produktrückruf (Field Safety Corrective Action)** eingeleitet, bitte bestätigen Sie dass sie den Verbleib der betroffenen Artikel geprüft haben. Der Verbleib der betroffenen Artikel wurde mit folgendem Ergebnis überprüft:

*For the above mentioned products a field safety corrective action is initiated. Please confirm that all affected products under your control were checked and identified. The disposition of products was checked with the following result:*

Auswertung / Evaluation				
Part/Lot	Anzahl Qty	Verbleib/ Disposition		
		<input type="checkbox"/> Original packaging	Qty _____	
		<input type="checkbox"/> In sets identified	Qty _____	
		<input type="checkbox"/> used / discarded	Qty _____	
Wichtige Informationen/ Important Informations				
<p>➤ <b>Bitte Senden Sie dieses Formular ausgefüllt innerhalb 24 h zurück an <a href="mailto:return@medartis.com">return@medartis.com</a></b>  <i>Please return this form within 24h to <a href="mailto:return@medartis.com">return@medartis.com</a></i></p> <p>➤ <b>Bitte senden Sie die betroffenen Produkte umgehend zurück</b>  <i>Please return all affected products immediately</i></p> <p>➤ <b>Bei Abschluss dieses Produktrückrufes werden wir Sie über getroffene Massnahmen informieren</b>  <i>You will receive further information upon closure of this field safety corrective action</i></p>				
		NAME / FUNCTION	DATUM / DATE	UNTERSCHRIFT / SIGNATURE
	<b>Bearbeitet durch</b> <i>Filled by</i>			



Produktrücksendung an:

Medartis AG  
 Hochbergerstrasse 60E  
 4057 Basel  
 z.H. Compliance & Vigilance