



<b>SUBJECT</b>	<b>UNIMED medical devices not covered by the CE marking due to a change of classification.</b>	<b>Notice #</b>	FSCA-2018-001
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**Medical devices concerned by this corrective action**

Medical devices (needles) listed below are concerned by this field safety corrective action (FSCA).

P/N	Description	P/N	Description
22.102	Needle Laborde/Sebrecht Luer Lock	25.111	Needle Seldinger Luer Lock
22.104	Needle Küss/Dupouy Luer Lock	25.112	Needle Seldinger Luer Lock
22.106	Needle Sise-Antoni Luer Lock	25.113	Needle Seldinger Double Luer Lock
22.110	Needle Dattner Luer Lock	25.114	Needle Seldinger Double Luer Lock
22.116	Needle Quincke-Babcock Luer Lock	25.115	Needle Arteriography Luer Lock
22.118	Needle Quincke-Babcock Luer Lock	25.125	Needle Hunt Luer Lock
22.131	Needle Lumbal Stylet Luer Lock	25.129	Needle Curry Luer Lock
22.132	Needle Lumbal Stylet Luer Lock modified	25.135	Needle Vertebralis Luer Lock
22.136	Needle Lumbal-8-Luer Olive	25.137	Needle Karras Luer Lock
22.141	Needle Barker-Bier Luer Lock	25.140	Needle Myelgraphy Luer Lock
22.143	Needle Fleischer Luer Lock	25.141	Needle Cuatico Luer Lock
22.153	Needle Stenstroem Luer Lock	25.146	Needle Brockenbrough Adult Luer Lock, curved *
22.406	Needle Cushing Luer Lock	25.147	Needle Brockenbrough Adult Luer Lock, straight *
22.407	Needle Cushing Luer Olive	25.148	Needle Brockenbrough Child Luer Lock, curved *
22.410	Needle Frazier Luer Olive	25.149	Needle Brockenbrough Child Luer Lock, straight *
22.481	Needle Franzén Luer Lock	25.205	Needle Quincke-Aorto Luer Lock
22.485	Needle Franzén Instrumentarium	25.207	Needle Dos Santos Luer Lock
25.101	Needle Courmand Luer Lock	25.208	Needle Dos Santos modified Luer Lock
25.105	Needle Seldinger modified Luer Lock	25.209	Needle Aorto-Lateral Luer Lock
25.107	Needle Seldinger modified Luer Lock	25.211	Needle Aorto-Double Luer Lock
25.108	Needle Seldinger modified Luer Lock	25.214	Needle Tuohy Lumbar Aorta Luer Lock

\* Medical device present in the catalog but removed from sale in April 2008.

<b>Problem description</b>	Medical devices (needles) concerned by this notice have been reclassified from class IIa to class III by the M5 version of the European directive 93/42/EEC, released on the 09.21.2007.
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<b>Problem details</b>	<p>These medical devices have been sold on the market for more than 30 years.</p> <p>The medical devices concerned by this notice were classified in class IIa using rule #6 of the first version of the European directive on 09.21.1993.</p> <p>This rule contains a new exception for a new classification in class III, introduced with version M5 of the European directive 93/42/EEC in 2007:</p> <ul style="list-style-type: none"> <li>- Medical devices intended specifically for use in direct contact with the central nervous system.</li> </ul> <p>The medical devices concerned by this notice answered to this exception and are, from now on, classified in class III.</p> <p>The necessary technical documentation for CE marking of these medical devices is not adapted or complete enough to cover class III medical devices.</p>
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<b>Field safety notice (FSN) associated</b>	FSN-2018-001, requesting to immediately stop selling the concerned medical devices. <i>Sent on the 20<sup>th</sup> of December 2018 to the concerned national competent authorities and customers.</i>
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unimed

www.unimed.ch

# FIELD SAFETY CORRECTIVE ACTION

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<b>Corrective action</b>	<p><b><u>Type of corrective action: Product recall.</u></b></p> <p>All medical devices concerned by this notice must be removed from the market.</p> <p>If the customer is a distributor and/or an importer, the following actions must be conducted:</p> <ul style="list-style-type: none"><li>- Immediately transmit this notice to their distributors or final users for its application.</li><li>- Return to UNIMED or destroy all concerned medical devices by 29<sup>th</sup> of March 2019.</li></ul> <p>If the customer is the final user, the following action must be conducted:</p> <ul style="list-style-type: none"><li>- Return to UNIMED or destroy all concerned medical devices by 29<sup>th</sup> of March 2019.</li></ul>
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<b>Contact</b>	<p>A specific list of medical devices can be provided per initial distribution per customer and/or per country.</p> <p>To get this product list, send an email with your request to: <a href="mailto:info@unimed.ch">info@unimed.ch</a></p>
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## Acknowledgment form

<b>Customer</b> <i>Name</i> <i>Address</i> <i>Country</i>	
<b>Customer contact details</b> <i>Name/Function</i> <i>Email</i> <i>Phone</i>	
<b>Type of customer</b>	<input type="checkbox"/> Importer <input type="checkbox"/> Distributor <input type="checkbox"/> Final user

<b>Confirmation of the realization of required corrective actions</b>	<p>I acknowledge having conducted the following corrective actions:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Transmitted this notice for application to my distributors and/or importers and ensured the realization of these corrective actions.</li> <li><input type="checkbox"/> Transmitted this notice for application to my final users and ensured the realization of these corrective actions.</li> <li><input type="checkbox"/> Returned all concerned medical devices from my stock to UNIMED.</li> <li><input type="checkbox"/> Destroyed all concerned medical devices from my stock.</li> </ul> <p>Name: _____</p> <p>Function: _____</p> <p>Date: _____</p> <p>Signature: _____</p>
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