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# URGENT FIELD SAFETY NOTICE

Rue du Grand-Pré 10
1007 Lausanne
Switzerland
Tel: +41 21 624 21 51
Fax: +41 21 624 53 32
info@unimed.ch

| SUBJECT | **UNIMED medical devices not covered by the CE marking due to a change of classification.** | **Notice #** | FSN-2018-001 |
|---|---|---|---|

## Medical devices concerned by this notice

Medical devices (needles) listed below are concerned by this notice.

| P/N | Description |
|---|---|
| 22.102 | Needle Laborde/Sebrecht Luer Lock |
| 22.104 | Needle Küss/Dupouy Luer Lock |
| 22.106 | Needle Sise-Antoni Luer Lock |
| 22.110 | Needle Dattner Luer Lock |
| 22.116 | Needle Quincke-Babcock Luer Lock |
| 22.118 | Needle Quincke-Babcock Luer Lock |
| 22.131 | Needle Lumbal Stylet Luer Lock |
| 22.132 | Needle Lumbal Stylet Luer Lock modified |
| 22.136 | Needle Lumbal-8-Luer Olive |
| 22.141 | Needle Barker-Bier Luer Lock |
| 22.143 | Needle Fleischer Luer Lock |
| 22.153 | Needle Stenstroem Luer Lock |
| 22.406 | Needle Cushing Luer Lock |
| 22.407 | Needle Cushing Luer Olive |
| 22.410 | Needle Frazier Luer Olive |
| 22.481 | Needle Franzén Luer Lock |
| 22.485 | Needle Franzén Instrumentarium |
| 25.101 | Needle Cournand Luer Lock |
| 25.105 | Needle Seldinger modified Luer Lock |
| 25.107 | Needle Seldinger modified Luer Lock |
| 25.108 | Needle Seldinger modified Luer Lock |

| P/N | Description |
|---|---|
| 25.111 | Needle Seldinger Luer Lock |
| 25.112 | Needle Seldinger Luer Lock |
| 25.113 | Needle Seldinger Double Luer Lock |
| 25.114 | Needle Seldinger Double Luer Lock |
| 25.115 | Needle Arteriography Luer Lock |
| 25.125 | Needle Hunt Luer Lock |
| 25.129 | Needle Curry Luer Lock |
| 25.135 | Needle Vertebralis Luer Lock |
| 25.137 | Needle Karras Luer Lock |
| 25.140 | Needle Myelgraphy Luer Lock |
| 25.141 | Needle Cuatico Luer Lock |
| 25.146 | Needle Brockenbrough Adult Luer Lock, curved * |
| 25.147 | Needle Brockenbrough Adult Luer Lock, straight * |
| 25.148 | Needle Brockenbrough Child Luer Lock, curved * |
| 25.149 | Needle Brockenbrough Child Luer Lock, straight * |
| 25.205 | Needle Quincke-Aorto Luer Lock |
| 25.207 | Needle Dos Santos Luer Lock |
| 25.208 | Needle Dos Santos modified Luer Lock |
| 25.209 | Needle Aorto-Lateral Luer Lock |
| 25.211 | Needle Aorto-Double Luer Lock |
| 25.214 | Needle Tuohy Lumbar Aorta Luer Lock |

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

| **Problem description** | 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 09.21.2007. |
|---|---|

| **Problem details** | These medical devices have been sold on the market for more than 30 years.<br><br>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.<br><br>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:<br>- Medical devices intended specifically for use in direct contact with the central nervous system.<br><br>The medical devices concerned by this notice answered to this exception and are, from now on, classified in class III.<br><br>The necessary technical documentation for CE marking of these medical devices is not adapted or complete enough to cover class III medical devices. |
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| **Problem impact** | The review of the clinical evaluation report of these medical devices shows that there is no impact linked to their performance or patient safety.<br><br>The review of the complaints received since 1992 (year of UNIMED complaint system implementation) shows that no customer complaint has been placed related to the problem of use or functionality of these medical devices.<br><br>No return has been made from a national competent authority regarding a safety problem linked to the use of these medical devices.<br><br>Based on clinical evaluation and post-market surveillance, no performance issue or patient safety problem was found with respect to these medical devices. |

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| **UNIMED corrective action** | As soon as this issue was detected by our notified body during the audit which took place on 11th and 12th of September 2018, UNIMED decided to remove these medical devices from production and sale.<br><br>The following actions have been conducted by UNIMED:<br>- Informed concerned customers by email of the stopping of production and sale of these medical devices, requiring them to request that their customers stop selling or using them.<br>- Destruction of the components and medical devices in stock at UNIMED.<br>- Removed the catalog of medical devices from UNIMED website.<br>- Blockage of the production management system to prevent the creation of any manufacturing work orders related to these medical devices. |

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| **Customer corrective action** | All medical devices concerned by this notice must be removed from the market.<br><br>If the customer is a distributor and/or an importer, the following actions must be conducted:<br>- Stop selling these medical devices immediately.<br>- Immediately transmit this notice to their distributors or final users for its application.<br>- Return to UNIMED or destroy all concerned medical devices by 29th of March 2019.<br><br>If the customer is the final user, the following actions must be conducted:<br>- Stop using these medical devices immediately.<br>- Return to UNIMED or destroy all concerned medical devices by 29th of March 2019. |

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| **Acknowledgment form** |
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| This form must be sent back in 1 or 2 times:<br>1) First, when signed after reading and acknowledging this notice.<br>2) Second, when signed after all corrective actions have been conducted. |

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|---|---|
| **Customer**<br>*Name*<br>*Address*<br>*Country* | |
| **Customer contact details**<br>*Name/Function*<br>*Email*<br>*Phone* | |
| **Type of customer** | ☐ Importer ☐ Distributor ☐ Final user |

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| **1) Notice acknowledgment** | I acknowledge that I have read and understood this notice and accept implementation of all required corrective actions.<br><br>Name: _____<br><br>Function: _____<br><br>Date: _____<br><br>Signature: _____ |
| **2) Confirmation of the realization of required corrective actions** | I acknowledge having conducted the following corrective actions:<br>☐ Transmitted this notice for application to my distributors and/or importers and ensured the realization of these corrective actions.<br>☐ Transmitted this notice for application to my final users and ensured the realization of these corrective actions.<br>☐ Returned all concerned medical devices from my stock to UNIMED.<br>☐ Destroyed all concerned medical devices from my stock.<br><br>Name: _____<br><br>Function: _____<br><br>Date: _____<br><br>Signature: _____ |