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URGENT FIELD SAFETY NOTICE

Rue du Grand-Pré 10
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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 Franzen Luer Lock
22.485	Needle Franzen 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 Brokenbrough Adult Luer Lock, curved *
25.147	Needle Brokenbrough Adult Luer Lock, straight *
25.148	Needle Brokenbrough Child Luer Lock, curved *
25.149	Needle Brokenbrough 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 catalogue but removed form sales 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 the 21.09.2007.

Problem details	These medical devices have been sold on the market for more than 30 years. The concerned medical devices by this notice have been classified in class IIa using the rule # 6 of the first version of the European directive in 21.09.1993. 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: - Medical devices intended specifically for use in direct contact with the central nervous system. The concerned medical devices by this notice answered to this exception and are from now on classified in class III. The necessary technical documentation for CE marking of these medical devices is not adapted and 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 and the patient safety. The review of the complaints received since 1992 (year of UNIMED complain system's implementation) shows that no customers complaint have been placed related to problem of use or functionality of these medical devices. No return has been made form a national competent authority regarding a safety problem linked to the use of these medical devices. Based on clinical evaluation and post market surveillance, no performance issue or patient safety problem was found with respect to these medical devices.

UNIMED corrective action	As soon as this issue was detected by our notified body, during the audit which took place on the 11 and 12 of September 2018 UNIMED decided to remove these medical devices from production and sales. The following actions have been conducted by UNIMED: - Inform concerned customers by emails of the stop of production and sales of these medical devices and require them to request their customers to stop selling or using them. - Destruction of the components and medical devices in stock at UNIMED. - Remove the catalogue of medical devices from UNIMED internet website. - Blockage of the production management system to prevent any creation of manufacturing work order related to these medical devices.

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

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Acknowledgement form
This form must be send back in 1 or 2 times: 1) First time signed when red and the acknowledgement of this notice is done. 2) Second time signed when all corrective actions are conducted.

Customer *Name* *Address* *Country*	
Customer contact details *Name / Function* *Email* *Phone*	
Type of customer	☐ Importer ☐ Distributor ☐ Final user

1) Notice acknowledgment	I acknowledge that I have red and understood this notice and accept implementation of all required corrective actions Name : _____ Function : _____ Date : _____ Signature : _____
2) Confirmation of the realization of required corrective actions	I acknowledge having conducted the following corrective actions: ☐ Transmit this notice for application to my distributors and/or importers and ensure the realization of these corrective actions. ☐ Transmit this notice for application to my final users and ensure the realization of these corrective actions. ☐ Ship back all concerned medical devices from my stock to UNIMED. ☐ Destroy all concerned medical devices from my stock. Name : _____ Function : _____ Date : _____ Signature : _____