



SUBJECT	CHANGE MANAGEMENT	SHEET #	CHANGEMENT.FIE
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The following table summarize all potential changes conducted by Unimed impacting their products and Unimed organization and their type of notifications.

No notification to customer.			
Notification to customer before implementation.			
Notification and approval from customer before implementation.			
1.	Product		
1.1	Change customer product specification	X	
1.2	Change customer product specification within customer requirement		X
2.	Production		
2.1	Machine, tool, jig		
2.1.1	Change between existing and/or new equivalent equipment		X
2.1.2	Relocation within the production facility		X
2.1.3	Change of tool, not impacting directly the product		X
2.1.4	Change of tool, impacting directly the product	X	
2.1.5	Change of short-lived tool		X
2.1.6	Change of jig		X
2.1.7	Use of production equipment after a long production interruption		X
2.2	Process		
2.2.1	Change sequence of existing process steps		X
2.2.2	Adding/withdrawing/modification of a process step not impacting directly the product *		X
2.2.3	Adding/withdrawing/modification of a process step impacting directly the product *	X	
2.2.4	Change from internal to outsourced equivalent technological process		X
2.2.5	Change to another technological process without any influence on the result *		x
2.2.6	Change to another technological process giving equivalent result but with direct impact on product *	X	
2.2.7	Change of validated process	X	
2.2.8	Changes inside validated tolerance limits of process parameters		X
2.2.9	Change of acceptance criteria *	X	
2.2.10	Change of internal acceptance criteria within customer requirements *		X
2.2.11	Change of raw material supplier affecting the product specification *	X	
2.2.12	Change of component supplier affecting the product specification *	X	
2.2.13	Change of auxiliary materials, liquids and supplies used		X
2.3	Packaging / Labelling		
2.3.1	Change of standard packaging and/or labelling		X
2.3.2	Change of specified customer packaging and/or labelling	X	
3.	Supplier		
3.1	Change of name, address and company form		X
3.2	Relocation within the production facility		X
3.3	Change production site		X
3.4	Change of equivalent production machine		X
3.5	Change of process		X
4.	Company		
4.1	Change of Unimed structure, organisation, management, employees		X
4.2	Change of production site	X	
4.3	Change in certification status **		X
4.4	Change in the scope of certification **		X

All this information are for reference only. They have no legal or contractual commitment Unimed SA.

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\* Direct impact on product = Significant change = Change impacting directly product **Form, Fit** and/or essential **Function**.

With:

- **Form** is the shape, size, dimensions, mass or other visual parameters which uniquely characterise an item.
- **Fit** is the ability of an item to physically interface with all other components, including tolerances.
- **Function** refers to the performance that a product has been designed for and communicated in writing to Unimed.

\*\* Last versions of certificates are available on Unimed website [www.unimed.ch](http://www.unimed.ch).

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