



|         |                   |         |                |
|---------|-------------------|---------|----------------|
| SUBJECT | CHANGE MANAGEMENT | SHEET # | CHANGEMENT.FIE |
|---------|-------------------|---------|----------------|

The following table summarize all potential changes conducted by Unimed impacting their products and Unimed organization and their type of notifications.

|                                                                       |                                                                                                      |   |   |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|---|---|
| <b>No notification to customer.</b>                                   |                                                                                                      |   |   |
| <b>Notification to customer before implementation.</b>                |                                                                                                      |   |   |
| <b>Notification and approval from customer before implementation.</b> |                                                                                                      |   |   |
| <b>1.</b>                                                             | <b>Product</b>                                                                                       |   |   |
| 1.1                                                                   | Change customer product specification                                                                | X |   |
| 1.2                                                                   | Change customer product specification within customer requirement                                    |   | X |
| <b>2.</b>                                                             | <b>Production</b>                                                                                    |   |   |
| 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 |   |
| <b>3.</b>                                                             | <b>Supplier</b>                                                                                      |   |   |
| 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 |
| <b>4.</b>                                                             | <b>Company</b>                                                                                       |   |   |
| 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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