



**Tyvek® Transition Checklist – Rev 2**

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**Change Notification ID:** \_\_\_\_\_

Please use one checklist for each packaging material combination

|  |  |
|--|--|
| Applicant                              |  |
| Affected certificates:                 |  |
| Address                                |  |
| Packaging Facility:<br>(or Facilities) |  |

**Note:** This Checklist is only intended for new materials that are equivalent to existing materials. If there are changes to the Tyvek® or base material (e.g. change from 1059B to 1073B, change from uncoated to coated material or implementation of a different base material), this must be clearly stated in the Change Notification.

**Guidance on application:**

Section 1,2 and 3 are related to traceability of the data to certified products. Please be aware that any change of the product or process besides the material would have to be handled as an own significant change of a sterile product.

Section 4 deals with the risk assessment taking into account the DuPont Tyvek® data to come up with a conclusion what further testing may be necessary. References to supporting data may be provided in this section.

Section 5 provides space to enter testing data to substantiate claims in the risk assessment - where necessary.

**1. Product information:**

|                               |                                     |            |
|-------------------------------|-------------------------------------|------------|
| Product family/families:      |                                     |            |
| Directive:                    |                                     |            |
| MDD /AIMDD class:             |                                     |            |
| Sterilization method(s) used: | <input checked="" type="checkbox"/> |            |
|                               | <input type="checkbox"/>            | EO         |
|                               | <input type="checkbox"/>            | Gamma      |
|                               | <input type="checkbox"/>            | E-Beam     |
|                               | <input type="checkbox"/>            | X-Ray      |
|                               | <input type="checkbox"/>            | Moist heat |
| Other:                        |                                     |            |

**2. Packaging material information:**

| Question   | Statement/Explanation by the manufacturer | Source of information (manufacturers controlled documents: Doc. Nr. and page) |
|--|---|---|
| Tyvek® type:   | <input checked="" type="checkbox"/>       |   |
|  | <input type="checkbox"/>                  | 1059B uncoated  |
|  | <input type="checkbox"/>                  | 1059B coated  |
|  | <input type="checkbox"/>                  | 1073B uncoated  |
|  | <input type="checkbox"/>                  | 1073B coated  |
| Packaging type (e.g. Rigid Blister, Soft Blister, Pouch...): |   |   |

**3. Packaging process information:**

| Question   | Statement/Explanation by the manufacturer | Source of information (manufacturers controlled documents: Doc. Nr. and page) |
|--|---|---|
| Was a packaging family approach chosen based on the same materials and thicknesses only differing in size? | Requirement: EN ISO 11607-2:2006 5.1.5    |   |