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Product Service

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	Second Information to Transition of Tyvek® material	mhs-crt@tuev-sued.de	+49 89 5008-4327	2019-06-21	1 of 2

Second Information to Transition of Tyvek® material

Dear Sir or Madam,

Regarding the information to transitioning of Tyvek® material, the TÜV SÜD Product Service GmbH (TÜV SÜD) would hereby like to update their first customer letter dated 02.03.2012 on this subject. In addition, TÜV SÜD would like to update the information conveyed through the TÜV SÜD white paper dated (2018, V-M/MHS/16.1/en/SG) in relation to Tyvek®. This customer information replaces the aforementioned customer letter and the white paper.

Please be informed that the legal manufacturer is obliged to inform his Notified Body about every planned Tyvek® transition by submitting a substantial change notification.

The manufacturer / authorised representative shall inform the notified body of any change which could affect conformity with the essential requirements. According to the EC Directives, essential requirements are both the basic and the general product specific requirements.

Therefore, a change in a product specific requirement that could affect conformity with the essential requirements (general requirements) is deemed to be substantial and the notified body must be informed.
Changes that could affect conformance with essential requirements include changes to:

- Substantial quality system,
- Design specifications including packaging,
- Manufacturing processes, facility or equipment and/or
- Sterilization.

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According to the EC Directives, packaging of devices that are delivered in sterile condition is categorized as a product specific requirement and thus an essential requirement regarding the device. Therefore, it is not only the quality system which might be affected by Tyvek® material change (formal Tyvek® transition) but also a product specific requirement.
That means a change in the packaging, including a Tyvek® transition, is a change in an essential requirement which needs further approval of the notified body, independent of the device classification.

Please be informed, that the Notified Body TÜV SÜD is obliged to take action if there is doubt whether the essential requirements for the certificate are still fulfilled.

If you would like to submit a change notification as regards Tyvek® transition, please submit the change notification to your local contact at the TÜV SÜD Group.

Yours sincerely,

TÜV SÜD Product Service GmbH

i.V. Medical Health Service - Head of Certification Body

Stefan Preiß

i.A. Department Manager of General Essential Modules

Dr. Jan Havel