

INEOS Styrolution Group GmbH · Mainzer Landstraße 50 · D-60325 Frankfurt am Main

To whom it may concern

08 August 2016

Notice for customers, who intend to use INEOS Styrolution products in medical devices and/or pharmaceutical applications

INEOS Styrolution produces a wide variety of high quality materials that satisfy the manifold requirements of our customers, including products that may meet the specifications of customers for use in medical devices and pharmaceutical applications. INEOS Styrolution has a proven track record in supporting and working with our customers in the innovative use and application of our materials.

INEOS Styrolution has a diverse product portfolio and offers various healthcare packages. These packages will vary from product to product, but may include: notification of change agreements (with a signed long term supply contract), locked formulations as defined in a Drug Master File (DMF) filed with the FDA, a variety of regulatory compliance documents (e.g. food contact statements), and biocompatibility information based on testing performed on our pellets (USP Class VI, ISO 10993, etc.).

While INEOS Styrolution has performed some biocompatibility tests and assessed its products against various regulatory requirements, it has not designed or tested its products with respect to all of the special requirements related to their use in specific medical devices (including in-vitro diagnostic devices, defined in Risk Classes I, II and III according to the European and US Medical Device legislation) and pharmaceutical applications, including packaging of parenteral and ophthalmic products and inhalers ("**Medical Applications**"). Accordingly, unless it is agreed to in written form with a customer and/or defined by the respective product specification, INEOS Styrolution does not claim that its products are suitable or fit for any specific Medical Application and INEOS Styrolution only warrants that its products meet the specifications listed on the applicable product specification.

The customer, having the expertise and the knowledge in the intended use of an INEOS Styrolution product, has to establish, based on his own experience and tests, that the INEOS Styrolution product/s selected and specified by him for specific Medical Applications is/are safe and suitable for use in such Medical Applications. The decision on the use of any of our products in a Medical Application is solely at the customer's risk and the customer has the sole responsibility to determine whether the use of one or more of our products in a Medical Application is safe, lawful, and technically suitable ("**Safe and Lawful Use**"). Moreover, we ask the customer to confirm that all appropriate and legally required testing has been and will continue to be performed to ensure the Safe and Lawful Use of our products at all times.

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If a customer intends to use INEOS Styrolution products in any Medical Application, the following principles – in addition to the above - generally apply:

Implants

Please be aware that INEOS Styrolution does not supply its products for the manufacture of implants in any risk class and specifically advises against the use of its products in these medical applications.

Risk Class I applications

Subject to an evaluation and a release in each individual case, INEOS Styrolution is prepared to supply Standard Food Contact Package¹ for medical applications within Risk Class I or for pharmaceutical applications such as solid dosage forms for oral applications. INEOS Styrolution's sole warranty with respect to such products shall be covered in the agreed product specifications.

Risk Class II applications

In regards to Risk Class II applications, INEOS Styrolution is prepared to supply specific products² for individual medical applications within such Risk Class (with the exception of implants) including packaging of parenteral and ophthalmic products as well as inhalers. This is, however, subject to a thorough examination of each specific case and the execution of a respective indemnity and disclaimer letter by the customer.

Risk Class III applications

INEOS Styrolution does not promote or encourage the use of its products in Risk Class III applications. Deviations to this guideline would need a detailed risk assessment completed, approval from the most senior INEOS Styrolution regional management (up to and including the Regional President), and specific indemnity and disclaimers agreed to by the customer.

Therefore we would kindly ask you to contact your INEOS Styrolution sales representative if you intend to use any INEOS Styrolution products in any Medical Application medical devices or pharmaceutical applications.

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¹ INEOS Styrolution products with EU and/or US food contact statements to be used in Risk Class I applications.

² Full Service HD products and Essential HD products as defined and listed in the HD brochure.