

SELF-DECLARATION

Assessment of the Suitability of the Vetro Power Nanocoating Material for Use in Medical Hygiene Pads

After reviewing the available scientific documentation and the biological characterisation of the Vetro Power nanocoating material, the following assessment has been reached:

The Vetro Power nanocoating material has undergone comprehensive biological characterisation. The available scientific documentation includes, in particular, chemical characterisation and biological evaluation in accordance with the relevant parts of DIN EN ISO 10993. This includes assessments of cytotoxicity, irritation, sensitization, hemocompatibility, implantation, histopathological evaluation, and dermatological compatibility.

The overall body of available scientific evidence demonstrates that the Vetro Power nanocoating material represents a scientifically well-founded material platform for applications involving direct and prolonged skin contact.

Based on the available evidence, there are no fundamental biological objections to the use of the Vetro Power nanocoating material as a component of medical hygiene products, including medical hygiene pads, provided that the respective finished product is designed, evaluated, validated, and manufactured in accordance with all applicable regulatory requirements.

This declaration relates exclusively to the assessment of the Vetro Power nanocoating material as a material platform. It does not replace the product-specific risk assessment, conformity assessment, or regulatory approval required for the respective medical device.

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