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Product Information

Product: Ultrasint PA 11

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Results of the testing as required by the ISO10993-1:2018 to be conducted for the intact skin assessment:

Cytotoxicity Testing- XTT: passed
(ISO 10993-5 (2009))
In vitro Skin Irritation Testing- Human Skin Model: passed
(ISO 10993-10 (2013); OECD Guideline No. 439)
In vivo Sensitisation Testing- Local Lymph Node Assay: passed
(ISO 10993-10 (2013); OECD Guideline No. 429)

Final Assessment: Accepted for the use on intact skin

However, the biocompatibility tests were recorded on test specimen of the above referenced product to show compatibility of the material in general, the biocompatibility tests listed are not part of any continuous production protocol. The test assessments shows the grade of acceptability on the intact skin, however it reflects only the test specimen and has to be retested on the final product.

F o r n o t i c e:
We give no warranties, expressed or implied, concerning the suitability of above-mentioned product for use in any medical device and pharmaceutical applications.

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