



Certificate of compliance for biocompatibility tests

Testmaterial:

PA1101 refreshed powder (50% new powder + 50% recycled powder

from EOSINT P System)

Batch No.:

919822

Sterility/Sterilisation

Unsterile

method:

Supplier:

EOS GmbH, Electro Optical Systems, Robert-Stirling-Ring 1, 82152

Krailing, Germany

Studies performed:

The following study was performed in order to determine the biocompatibility of the product PA1101 refreshed powder (50% new powder + 50% recycled powder from EOSINT P System) using *in vivo*

methods according to ISO 10993-1, 10993-10 and 10993-12:

Irritation Test (Intracutaneous Reactivity) in the Rabbit

(BSL Munich Study No. 155805)

Skin Sensitisation (Guinea Pig Maximisation Test)

(BSL Munich Study No.155806 A/B)

Results:

The product did pass all requirements in the studies performed.

The biological tests did not show significant findings, so this part of

biocompatibility testing was fulfilled.

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