

BIOCOMPATIBILITY CERTIFICATE

Testmaterial: PA 2200

Supplier: EOS GmbH
Pasinger Strasse 2, D-82152 Planegg

Studies performed: The following studies were performed in order to determine the biocompatibility of the product PA 2200 according to ISO 10993-1:

CYTOTOXICITY

SENSITISATION, polar extract

SENSITISATION, non-polar extract

INTRACUTANEOUS REACTIVITY

Results: The product did not show any adverse effects in the studies performed. Therefore, the biocompatibility of the test material was proved.

BSL BIOSERVICE Scientific Laboratories GmbH Munich

Behringstraße 6

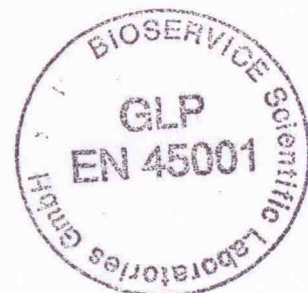
D-82152 Planegg



Dr. Achim Albrecht

Biological Safety Testing

Date: April 10, 2001



BIOCOMPATIBILITY Certificate

Test Item: PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System)

Supplier: EOS GmbH Electro Optical Systems
Robert-Stirling-Ring 1, 82152 Krailling, Germany

Studies performed: The following studies were performed in order to determine the biocompatibility of the product PA 2200 Reused powder (50% virgin + 50% recycled powder from EOSINT P System), Batch No. 919389 according to ISO 10993-1.

CYTOTOXICITY (BSL Study No. 094861)

SENSITISATION¹⁾ (BSL Study No. 094864)

INTRACUTANEOUS REACTIVITY (BSL Study No. 094863)

Results: The product did pass the requirements in the studies performed.
Therefore, the biocompatibility of the test material was proved.

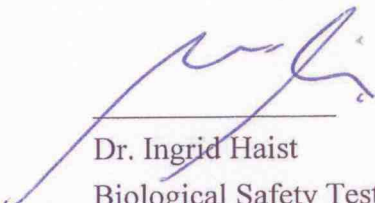
1) LLNA (Local Lymph Node Assay)

BSL BIOSERVICE Scientific Laboratories GmbH Munich

Behringstraße 6

82152 Planegg

Germany


Dr. Ingrid Haist

Biological Safety Testing

Date: 19 March 2010

BSL BIOSERVICE Scientific Laboratories GmbH

Behringstrasse 6/8 · 82152 Planegg, Germany
Telefon +49-(0)89-899 65 00 · Fax +49-(0)89-899 65 011
e-mail: info@bioservice.com · www.bioservice.com
Geschäftsführer: Dr. Wolfram Riedel
Amtsgericht München, HRB 109 770
Erfüllung und Gerichtsstand München
NORD/LB Norddeutsche Girozentrale, BLZ 250 500 00, Kto. 151 328 523, Swift-BIC: NOLADE2HXXX, IBAN: DE76 2505 0000 0151 3285 23
Deutsche Bank München, BLZ 700 700 24, Kto. 9 407 750, Swift-BIC: DEUTDE33MUC, IBAN: DE52 7007 0024 0940 7750 00



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-986.96.01

BIOCOMPATIBILITY CERTIFICATE

Testmaterial: Feinpolyamid PA 2200
Chemical composition: Polylaurinlactam

Supplier: EOS GmbH; Electro Optical Systems
Robert-Stirling-Ring 1, 82152 Krailling; Germany


Studies performed: The following study was performed in order to determine the biocompatibility of the device.

USP BIOLOGICAL TESTS (CLASSIFICATION VI/121 °C)

Results: The test item did not show any effect in the performed study and meets all the criterias of the USP Biological Tests Classification VI.

BSL BIOSERVICE Scientific Laboratories GmbH

Behringstraße 6
D-82152 Planegg


Dr. Ingrid Haist
Biological Safety Testing
Date: December 13, 2004

