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Certificate of Conformity (CoC)

According to DIN EN ISO 10993-5:2009-10

Certificate No.: A2 20211110 001
Test Report Ref. No.: 21AA0922 Version 1

Certificate Holder

Manufacturer Address	Notter GmbH In den Erlen 10 D-75248 Ölbronn
Contact Person	Mr. Harald Römer and Mr. Klaus Notter
Order number	21AA0922
Issuing date of the test report	25.06.2021
Issuing date of the CoC	10.11.2021

Product

Product	Plasmachrom®
Date of receipt of the product	31.05.2021
Condition	The test samples arrived undamaged and individually packed.
Identification	Description Tablettierwerkzeug mit PVD-Schicht Plasmachrom® Art. No. N/A Lot No. A, Cr0642

Tested according to

Standard / Guideline	DIN EN ISO 10993-5:2009-10 21 CFR Part 58 (Gesetz zum Schutz vor gefährlichen Stoffen [Chemikaliengesetz – ChemG] § 19b Abs.1 Chemikaliengesetz)
Deviation / Remarks	An uncoated sample showed a cytotoxic result (study 21AA0921).

This certificate refers to the above mentioned product. This is to certify that the test sample is in conformity with the requirements of DIN EN ISO 10993-5:2009-10 **to confirm biocompatibility regarding cytotoxicity**. The holder of the certificate is entitled to use this certificate for the declaration of conformity according to DIN EN ISO 10993-5:2009-10 and 21 CFR Part 58. This certificate does not imply assessment of the production of the product. Detailed specification of the tested product are shown in the above mentioned test report.

This certificate is valid provided that the test specifications and construction of the product remain unchanged and refers only to the product tested as received by the laboratory and cannot be transferred to other products.

Ansbach, 10.11.2021



Dr. Katrin Sulzer
Head of BioLabs

Dokumentnummer	Version	Autor	freigegeben	Dokumentenquellname
FB-BL-106	V2	KS	PH 19.10.2021	FB-BL-106_CoC_21AA0922_2021-11-10_V2