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Certificate of Conformity (CoC)

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

Certificate No.: A2 20221213 001

Test Report Ref. No.: 22AA1289 Version 1

Certificate Holder

Manufacturer Address	Notter GmbH In den Erlen 10 D-75248 Ölbronn		
Contact Person ^{#1}	Mr. Fabian Seifried		
Order number	22AA1289		
Issuing date of the test report	23.11.2022		
Issuing date of the CoC	Version 1	13.12.2022	
	Version 2	17.01.2023	

#1 At the customer's request, the contact person was adapted.

Product

Product	Schichtsystem ""a-C:H:Si (a-DLC)""		
Date of receipt of the product	20.01.2022		
Condition	The test samples arrived undamaged and individually packed.		
Identification	Description	Schichtsystem ""a-C:H:Si (a-DLC)"" Prozess DLC-Medtech Beschichtung durchgeführt durch Kunde am 18.01.2022	
	Art. No.	DLC-ID 2224	
	Lot No.	Charge PACVD	

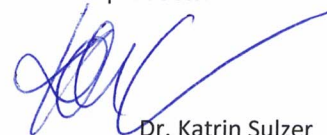
Tested according to

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)
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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, 17.01.2023



Dr. Katrin Sulzer
Head of BioLabs

This is an amended CoC from the V1 dated 13.12.2022 (FB-BL-106_CoC_22AA1289_2022-12-13_V1). Changes can be tracked via "#".

Dokumentnummer	Version	Autor	freigegeben	Dokumentenquellname
FB-BL-106	V2	KS	PH 19.10.2021	FB-BL-106_CoC_22AA1289_2023-01-17_V2