



ENTWICKLUNG | FERTIGUNG | VERTRIEB & SERVICE
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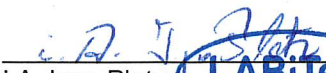
EC Declaration of Conformity

Name of Manufacturer:	LABiTec LABor BioMedical Technologies GmbH
Manufacturer Address:	An der Strusbek 6 22926 Ahrensburg, Germany
European Single Registration Nr. (SRN)	DE-MF-000020928
Product:	Cuvette Micro Refer to attachment
Intended Purpose:	The cuvettes hold samples and reagents for the measurement of the analyte. Accessory intended to be used for in-vitro diagnostic procedures only.
Basic UDI-DI (Basic Unique Device Identification)	4051088CUV211K8
Risk Classification: (Regulation (EU) 2017/746, Annex VIII, Rule 5b)	A
Registration No: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)	DE/CA01/161/051

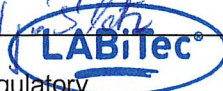
This declaration of conformity is issued under the sole responsibility of LABiTec LABOR BioMedical Technologies GmbH. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. This declaration is supported by the Quality System approval to ISO 13485. This declaration of conformity is valid until a revised conformity declaration is issued.

Signature:

Date (yyyy.mm.dd):


i.A. Ingo Platz
Support & Regulatory

2024-02-01


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Attachment to Declaration of Conformity

Product	Package size	Ref. No.
Cuvette micro, Dispo System	5x100 Cuvettes, incl. Mixer 1x4mm	211-01-090-00 211-10-050-00 211-07-010-00 211-09-050-00 211-01-600-00 211-16-050-00 40.613.0002
Cuvette micro, in plastic bag	1x500 Cuvettes and Mixer 1x4mm	211-01-100-00 211-10-070-00 211-24-070-00 40.611.0011
Cuvette micro, in plastic bag	5x500 Cuvettes and Mixer 1x4mm	211-01-130-00 211-21-080-00 211-01-620-00

