

EC-Declaration of Conformity

CE-IVD Marking (In-Vitro-Diagnostic-Devices)

Certificate



Hereby and with the CE-sign it is confirmed that following products, manufactured by **AHN Biotechnologie GmbH**, Uthleber Weg 14, D-99734 Nordhausen, Germany, meets the fundamental regulations of the directive of the council of the European community to the adjustment of legal rules of the member states regarding “**In-vitro-Diagnostics**” **98/79/EG, 27.10.1998**:

Product: AHN pipet4u[®] Manual Pipettes, Production Lot 2014

Serial Numbers: AA800001-ZZ899999

Product: AHN pipet4u[®] Revolution Electronic Pipettes, Production Lot 2014

Serial Numbers: AA100001-ZZ999999

Product: AHN pipet4u[®] OASIS Pipette Controller, Production Lot 2014

Serial Numbers: AA100001-ZZ999999

Product: AHN Racks for pipet4u[®] Pipettes, Production Lot 2014

Size: Racks for 4 and 6 Pipettes, Racks for 8 Channel Pipette

Product: AHN Pipette Tips and Pipette Filter Tips, Production Lot 2014

Volume ranges: 0.1-10 µl, 0.5-10/20 µl, 1-200 µl, 230 µl, 5-300 µl, 100-1000 µl, 1-5 ml, 1-5,5 ml, 1-10 ml

Product: AHN PCR Tubes, Production Lot 2014

Volume ranges: 0.2 and 0.5 ml Volume

Product: AHN Micro Tubes, Production Lot 2014

Volume ranges: 0.5 ml, 1.5 ml, 1.8 ml and 2.0 ml Volume

Product: AHN Spin Columns and Microfilterplates, Production Lot 2014

Volume ranges: 0.8 ml and 1 ml Volume

Product: AHN Rackboxes, Production Lot 2014

Sizes: 60-places and 96-places

Product: AHN ULTRAPrep[®] MiniPrep DNA-Purification Kits, Production Lot 2014

Sizes: 50 reactions and 250 reactions

To evaluate the conformity of the products, the following standards were taken into consideration:

European Standard **ISO 8655, part 1, part 2 and part 6**, piston operated volumetric apparatus and Pipette Tips. General obligation to notify pursuant to **§§ 25 and 30 (2) German Medical devices Act. European Standard 98/79/EG** for In-Vitro-Diagnostics Medical Devices. The standards used for the measurements are traceable to the national standards of the Federal Republic of Germany at the Physikalisch-Technische Bundesanstalt (PTB). Competent authority code **DE/CA90**, Thüringer Landesamt für Verbraucherschutz Dezernat 21 Technischer Verbraucherschutz, Marktüberwachung. This declaration is made under the sole responsibility of the producer.

AHN Biotechnologie GmbH

Quality Control Department

Uthleber Weg 14

D-99734 Nordhausen

Nordhausen, 2014-01-01

This document was sent online and is valid without signature

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**Certified
Quality
Management
System
DIN EN ISO
9001:2008**