

# 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 2016**

Serial Numbers: AA800001-ZZ899999

**Product: AHN pipet4u® Revolution Electronic Pipettes, Production Lot 2016**

Serial Numbers: AA100001-ZZ999999

**Product: AHN pipet4u® OASIS Pipette Controller, Production Lot 2016**

Serial Numbers: AA100001-ZZ999999

**Product: AHN Racks for pipet4u® Pipettes, Production Lot 2016**

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

**Product: AHN Pipette Tips and Pipette Filter Tips, Production Lot 2016**

Volume ranges: 0.1-10 µl, 0.5-10/20/30 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 2016**

Volume ranges: 0.2 and 0.5 ml Volume

**Product: AHN Micro Tubes, Production Lot 2016**

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

**Product: AHN Spin Columns and Microfilterplates, Production Lot 2016**

Volume ranges: 0.8 ml and 1 ml Volume

**Product: AHN Rackboxes, Production Lot 2016**

Sizes: 60-places and 96-places

**Product: AHN ULTRAPrep® MiniPrep DNA-Purification Kits, Production Lot 2016**

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, 2016-01-01

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**CEOs**

Torsten Buchwald  
Jeffrey Anthony Duchemin  
Robert Emery Gagnon  
Joseph Philip Eyles

**Address**

Uthleber Weg 14  
D-99734 Nordhausen

**Contact**

Phone.: +49(0)3631/46594-04  
+49(0)3631/47439-20  
Fax: +49(0)3631/46594-10  
Email: info@ahn-bio.de  
Web: www.ahn-bio.de

**Bank Account**

Commerzbank AG €/€  
Account No.: 6065155  
Bank Code: 82040000  
BIC: COBADE33  
IBAN: DE16820400000606515500

**Commercial Register**

HRB 404781  
Amtsgericht Jena  
VAT-ID No. DE812717024

**Certified**

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

# Autoclaving Certificate



AHN Biotechnologie tips, filter tips, racks and rackboxes, micro-tubes, cryotubes, spin columns, PCR-tubes, PCR-stripes and pipet4u micropipettors are produced from virgin polypropylene and are autoclavable. All items should be carefully cleaned before autoclaving to prevent baking contaminants into the surface of the plastic. After cleaning, all items should be rinsed thoroughly in distilled water before autoclaving. Certain chemicals which have no appreciable effect at room temperature may cause deterioration at autoclaving temperatures and therefore must be removed.

We recommend these tips, tubes, stripes and racks be autoclaved using the following specifications:

<b>Temperature</b>	<b>121° Celsius / 250° Fahrenheit</b>
<b>Pressure</b>	<b>1,05 bar / 15 psig (Pounds)</b>
<b>Time</b>	<b>15 minutes or less</b>

**NOTE:** Excessive heat and/or time in the autoclave can cause warping of both tips and racks !

**NOTE:** Dry heat sterilization of polypropylene which takes effect from 160° Celsius is not recommended. Dry heat sterilization with 121° Celsius or 250° Fahrenheit with no load and no stacking is possible overnight. Gas sterilization with ethylene oxide, formaldehyde is possible. We recommend allowing an appropriate aeration time suited to the particular application before reusing the item. Chemical disinfectants which are commonly-used (quaternary ammonium compounds, iodophors, formalin, benzalkonium chloride, ethanol etc.) can be used without problems.

**AHN Biotechnologie GmbH**

Quality Control Department

Uthleber Weg 14

D-99734 Nordhausen

Nordhausen, 1st of October 2009

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# DNase | RNase free

## Certificate



**AHN Biotechnologie GmbH** Pipette Tips and Filter Tips, Micro Tubes, Spin Columns PCR Tubes, Filter Microplates have been tested and are **certified free of DNase or RNase** contamination. Also **free of human DNA, pyrogene and free of PCR-inhibitors**.

All products are injection moulded under clean room environments according to **US-Fed. Std. 209, class 10.000 and German DIN-VDI Standard 2083**, which ensures the integrity of all AHN Tips and plastic products.

### DNase Test Procedure

Sample Tubes/Tips/Plates are pipetted with 60 µl sterile water and vortexed before being briefly spun down. The water from the first Tube/Tip is then transferred to the second. This procedure is repeated until the water has been exposed to all tubes/tips of the sample batch except the final one. 32 µl from the penultimate Tube/Tip is transferred to the last Tube/Tip/Plate where 8 µl of magnesium chloride solution and 5 µl of plasmid DNA are added. The Tube/Tip is left to incubate at 37° Celsius for 2 hours with a negative and three positive quantified controls. 1 µl EDTA is then added to each Tube/Tip/Plate to stop the reaction. The plasmid DNA mixture is then analysed on a 1.5% agarose gel. The incubated controls are run in parallel. The agarose gel is then stained using ethidium bromide. DNase contamination is indicated by a brighter band corresponding to the relaxed form of the plasmid, where the plasmid DNA has been nicked by DNases present. For samples to pass the certification, the relative intensities of the supercoiled and relaxed plasmid DNA bands from solutions exposed to the batch samples must correspond to the negative control.

### RNase Test Procedure

Sample Tubes/Tips/Plates are pipetted with 60 µl reaction buffer and vortexed before being briefly spun down. The reaction buffer from the first Tube/Tip is then transferred to the second. This procedure is repeated until the reaction buffer has been exposed to all Tubes/Tips of the sample batch except the final one. 40 µl from the penultimate Tube/Tip/Plate are transferred to the last Tube/Tip and 5 µl of tRNA is added. The Tube is left to incubate at 37° Celsius for 2 hours with a negative and three quantified positive controls. The tRNA mixture is then analysed on a 4 % agarose gel. The incubated controls are run in parallel. The agarose gel is then stained using ethidium bromide. RNase contamination is indicated by a smear, where the tRNA has been degraded by RNases present. For samples to pass the certification, the tRNA band from solutions exposed to the batch samples must be intact with no signs of smearing.

**AHN Biotechnologie GmbH**  
Quality Control Department  
Uthleber Weg 14  
D-99734 Nordhausen

Nordhausen, 2015-01-01

This document was sent online and is valid without signature

<b>CEOs</b> Torsten Buchwald Jeffrey Anthony Duchemin Robert Emery Gagnon	<b>Address</b> Uthleber Weg 14 D-99734 Nordhausen	<b>Contact</b> Phone.: +49(0)3631/46594-04 +49(0)3631/47439-20 Fax: +49(0)3631/46594-10 Email: info@ahn-bio.de Web: www.ahn-bio.de	<b>Bank Account</b> Commerzbank AG €/€ Account No.: 6065155 Bank Code: 82040000 BIC: COBADE33HAN IBAN: DE168204000000606515500	<b>Commercial Register</b> HRB 404781 Amtsgericht Jena VAT-ID No. DE812717024	<b>Certified Quality Management System</b> <b>DIN EN ISO 9001:2008</b>
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# Pyrogen free

## Certificate



AHN Biotechnologie GmbH

**Pipette Tips**  
**Pipette Filter Tips**  
**PCR Tubes**  
**Micro Tubes**  
**Cryo Tubes**  
**Spin Columns**  
**Filter Microplates**

have been tested and are certified pyrogen free. These products from **AHN Biotechnologie GmbH** are manufactured in highly polished innovative molds under clean room environments according to **US-Fed. Std. 209, class 10.000 and German DIN-VDI Standard 2083**, which ensures the integrity of all AHN Tips.

The production of all AHN Tips fulfills the **DIN EN ISO 8655** standard for Pipette Tips and is permanently controlled according to **DIN 12600** by the official German gauging-office (Eichbehörde).

AHN Tips, PCR Tubes and Micro Tubes from AHN Biotechnologie GmbH are injection molded from autoclavable, non-wettable, virgin polypropylene on state of the art equipment in accordance with **DIN EN ISO 9001:2008** and DIN standard procedures. Only high quality, low adhesion, pyrogen free virgin polypropylene are used for these AHN products.

**AHN products are certified pyrogen free,**  
**less than 0.5 EU/ml**

Furthermore, all dyes used for our colored tips are guaranteed absolutely pyrogen free, eliminating the risk of sample contamination by trace elements.

Our strict quality control system, according to **DIN EN ISO 9001:2008** guarantees highest production safety.

**AHN Biotechnologie GmbH**  
Quality Control Department  
Uthleber Weg 14  
D-99734 Nordhausen

Nordhausen, 2015-01-01

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<b>CEOs</b> Torsten Buchwald Jeffrey Anthony Duchemin Robert Emery Gagnon Howard Pether	<b>Address</b> Uthleber Weg 14 D-99734 Nordhausen	<b>Contact</b> Phone.: +49(0)3631/46594-04 +49(0)3631/47439-20 Fax: +49(0)3631/46594-10 Email: info@ahn-bio.de Web: www.ahn-bio.de	<b>Bank Account</b> Commerzbank AG €/€ Account No.: 6065155 Bank Code: 82040000 BIC: COBADE33HAN IBAN: DE168204000000606515500	<b>Commercial Register</b> HRB 404781 Amtsgericht Jena VAT-ID No. DE812717024	<b>Certified Quality Management System</b> <b>DIN EN ISO 9001:2008</b>
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# GMP

## Certificate



Hereby and with the CE-sign it is confirmed that the production of the under mentioned laboratory products as well as the execution of operations specified below are carried out according to the WHO manufacturing practices for pharmaceutical products, **World Health Organization Technical Report Series 908, 37. Report, Geneva 2003.**

### Products:

1. Pipette Tips
2. Pipette Filter Tips
3. Micro Tubes
4. PCR Tubes
5. Spin Column Systems
6. Filter Microplates
7. Deep Well Microplates
8. Single Channel Pipettes
9. Multi Channel Pipettes
10. DNA Purification Kits

General obligation to notify pursuant to **§§ 25 and 30 (2) Medical Devices Act, MPG**, is done with registration number **DE/CA90/IVD-21** (CE-declaration). Competent authority code **DE/CA90**, Thüringer Landesamt für Lebensmittelsicherheit und Verbraucherschutz, Abteilung 2, Dezernat 24 (Pharmazie).

This certificate is issued due to the company inspection and is **valid for one year**. This declaration is made under the sole responsibility of the producer.

**AHN Biotechnologie GmbH**  
Quality Control Department  
Uthleber Weg 14  
D-99734 Nordhausen



Nordhausen, 2015-01-01

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#### CEOs

Torsten Buchwald  
Jeffrey Anthony Duchemin  
Robert Emery Gagnon

#### Address

Uthleber Weg 14  
D-99734 Nordhausen

#### Contact

Phone.: +49(0)3631/46594-04  
+49(0)3631/47439-20  
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Management  
System  
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9001:2008**

# Metal-free

## Certificate



AHN Biotechnologie GmbH

**Pipette Tips  
Pipette Filter Tips  
PCR Tubes  
Micro Tubes  
Spin Columns  
Filter Microplates**

are injection moulded from autoclavable, non-wettable, virgin polypropylene on state of the art equipment in accordance with **DIN EN ISO 9001:2008** and DIN standard procedures.

Only high quality, low adhesion, polypropylene are used for **AHN Biotechnologie GmbH** products. Our relentless pursuit to raise quality creates products that are always evolving to a higher standard.

### Guaranteed metal-free

Only high quality, low adhesion, polypropylene is used for AHN Biotechnologie GmbH Tips and Tubes. Furthermore, all dyes used for our colored Tips and Tubes are guaranteed absolutely metal-free. So even our „blues“ and „yellows“ are metal-free, eliminating the risk of sample contamination by trace elements.

Our strict quality control system, according to **DIN EN ISO 9001:2008** the German **DIN 12650** standard and **DIN EN ISO 8655** for Pipette Tips, is certified by the official German H-sign.

**AHN Biotechnologie GmbH**  
Quality Control Department  
Uthleber Weg 14  
D-99734 Nordhausen



Nordhausen, 2015-01-01

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#### CEOs

Torsten Buchwald  
Jeffrey Anthony Duchemin  
Robert Emery Gagnon

#### Address

Uthleber Weg 14  
D-99734 Nordhausen

#### Contact

Phone.: +49(0)3631/46594-04  
+49(0)3631/47439-20  
Fax: +49(0)3631/46594-10  
Email: info@ahn-bio.de  
Web: www.ahn-bio.de

#### Bank Account

Commerzbank AG €/€  
Account No.: 6065155  
Bank Code: 82040000  
BIC: COBADE33  
IBAN: DE16820400000606515500

#### Commercial Register

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Amtsgericht Jena  
VAT-ID No. DE812717024

#### Certified

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System  
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9001:2008**

# RoHS

## Compliance Certificate



**pipet4u® Single Channel Pipettes** and **pipet4u® Multi Channel Pipettes** from

**AHN Biotechnologie GmbH**

are manufactured from non-wettable, virgin plastic material on state of the art equipment in accordance with **DIN EN ISO 9001:2008** and DIN standard procedures.

**Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003**

On the restriction of the use of certain hazardous substances in electrical and electronic equipment

Hereby it is confirmed that **pipet4u® Single Channel Pipettes** and **pipet4u® Multi Channel Pipettes** manufactured by

**AHN Biotechnologie GmbH**  
**Uthleber Weg 14**  
**D-99734 Nordhausen**

meets the fundamental regulations of the Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003.

No AHN Biotechnologie GmbH products and no production raw material, resins, contains:

**Lead (Pb)**  
**Mercury (Hg)**  
**Cadmium (Cd)**  
**Hexavalent Chromium (Cr6+ Cr (VI))**  
**Polybrominated biphenyls (PBBs)**  
**Polybrominated dephenyl ethers (PBDEs)**

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# Sterilisation

## Certificate



**Pipette Filter Tips, sterile**

**Lot-No.: P-XXXXXX – P-XXXXXX**

Above **AHN Biotechnologie GmbH** products are certified **free of contamination (sterile)** according to:

**DIN EN 552 / ISO 11137**

The radiation has been performed in accordance to EN552/ISO 11137 as well as to product specification.

**DIN EN 556**

Sterilisation of medical products - requirements for sterile medical products.

<b>E-Beam – Radiation GSE 80</b>	Kind of radiation:	10 MeV
	Irradiation cycle:	15956 / SE 283 + SE 284
	Power:	8 mA
	Speed:	4,50 m/min
	Standard factor:	1,86

<b>Dosemapping</b>	Average Density:	0,181 g/cm3
	Area Gravity:	1,806 g/cm2
	Max. Dose:	37,7 kGy
	Min. Dose:	25,6 kGy
	Max./Min./s:	1,45 kGy

**SAL (Sterility Assurance Level)**

AHN sterile Tips and Filter Tips are sterile according to ISO 11137 and DIN EN 556 (**Caution:** if the packaging is undamaged). Customers of AHN Biotechnologie GmbH and customers of AHN Biotechnologie GmbH official distributors get a **2 years guarantee** on this Sterility Assurance Level, beginning with customers invoice date.

**AHN Biotechnologie GmbH**  
Quality Control Department  
Uthleber Weg 14  
D-99734 Nordhausen

Nordhausen, 2015-04-23



<b>CEOs</b> Torsten Buchwald Jeffrey Anthony Duchemin Robert Emery Gagnon	<b>Address</b> Uthleber Weg 14 D-99734 Nordhausen	<b>Contact</b> Phone.: +49(0)3631/46594-04 +49(0)3631/47439-20 Fax: +49(0)3631/46594-10 Email: info@ahn-bio.de Web: www.ahn-bio.de	<b>Bank Account</b> Commerzbank AG €/€ Account No.: 6065155 Bank Code: 82040000 BIC: COBADE33HAN IBAN: DE16820400000606515500	<b>Commercial Register</b> HRB 404781 Amtsgericht Jena VAT-ID No. DE812717024	<b>Certified Quality Management System</b> <b>DIN EN ISO 9001:2008</b>
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