



# CERTIFICAT CERTIFICATE

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Ind 1 – Décembre 21



**N° A768-NF EN ISO 13485 : 2016/A11 :2021**

Nous certifions par la présente que le Système de Management de la société :  
We hereby certify that the Management System of the company:

**Bio-Techne SAS**  
**19, RUE LOUIS DELOURMEL**  
**35230 NOYAL-CHATILLON-SUR-SEICHE (FRANCE)**

est conforme aux exigences de la norme suivante :  
is in compliance with the requirements of the following standard:

**NF EN ISO 13485 :2016/A11 :2021**

Le domaine d'application du Système de Management est le suivant :  
The scope of the Management System is:

**DISTRIBUTION DE DISPOSITIFS MEDICAUX DE DIAGNOSTIC IN  
VITRO : PRODUITS DE CONTROLES, CALIBRANTS ET KITS REACTIFS**  
*DISTRIBUTION OF IN VITRO DIAGNOSTIC MEDICAL DEVICES : CONTROLS,  
CALIBRATORS AND REAGENTS KITS.*

Ce certificat demeurera en vigueur jusqu'à sa fin de validité à moins d'avis contraire, à condition que la mise en place et la conformité du Système de Management soient jugées satisfaisantes lors des audits de surveillance et que les conditions du contrat de AB Certification soient observées.

This certificate is valid until its expiry date unless further notice, provided that the compliance and implementation of the Management System are found to be satisfactory at follow-up audits and that AB Certification contract rules are fulfilled.

Fait à PARIS, le 18 juillet 2022  
Signed in PARIS on the 18<sup>th</sup> of July 2022

Date de fin de validité : 26 septembre 2025  
Expiry date : 26<sup>th</sup> of September 2025

Date initiale de Certification : 27 septembre 2016  
Original Registration Date : 27<sup>th</sup> of September 2016

  
**Le Représentant d'AB Certification**  
AB Certification Representative

  
**Le Représentant de l'Entreprise**  
The Company Representative



America

# CERTIFICATE

Certificate Registration No: 951 21 5291

The Certification Body of  
**TÜV SÜD AMERICA INC.**

Certifies that the organization

**Bio-Techne Ltd**  
19 Barton Lane  
Abingdon - OX14 3NB United Kingdom

for the scope

**Sales, Marketing, Purchasing, Order Processing,  
Warehousing, Distribution and Customer Service  
of Life Science Research Products and Instruments**

Including the sites see enclosure

has established and applies an Environmental Management System.  
An audit was performed and has furnished proof that the requirements according to

## ISO 14001:2015

are fulfilled.

The certificate is valid from January 22, 2024 until January 21, 2027  
With a re-issue date on N/A

Greg Bates  
Director Business Assurance America  
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The validity of this certificate is contingent on the company maintaining its management system to the requirements of the indicated standard and is subject to regular monitoring by TÜV SÜD America.

TÜV®



America

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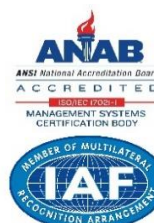
**Certificate Holder:****Bio-Techne Ltd**

19 Barton Lane

Abingdon, OX14 3NB United Kingdom

At the Sites	Specific Scope Site
<b>Bio-Techne Ltd</b> 19 Barton Lane, Abingdon - OX14 3NB United Kingdom	Central Function: Sales, Marketing, Purchasing, Order Processing, Warehousing, Distribution and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne GmbH</b> Borsigstrasse 7A, Wiesbaden 65205 Germany	Sales, Marketing and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne Ltd</b> Unit F, Heathrow West Business Park, Langley - SL3 8XP United Kingdom	Order Processing, Warehousing and Distribution of Life Science Research Products and Instruments
<b>Bio-Techne SAS</b> 19, Rue Louis Delourmel, CS 49228 Noyal Chatillon Sur Seiche, 35230 - Rennes, Cedex 9 France	Sales, Marketing, Purchasing, Order Processing, Warehousing, Distribution and Customer Service of Life Science Research Products and Instruments, IVD Controls and Calibrators

Greg Bates  
Director Business Assurance America  
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America

# CERTIFICATE

Certificate Registration No: 951 07 4360

**The Certification Body of  
TÜV SÜD AMERICA INC.**

Certifies that the organization

**Bio-Techne Ltd**

**19 Barton Lane  
Abingdon, OX14 3NB United Kingdom**

for the scope

**Sales, Marketing, Purchasing, Order Processing,  
Warehousing, Distribution and Customer Service  
of Life Science Research Products and Instruments**

Including the sites see enclosure

has established and applies a Quality Management System.  
An audit was performed and has furnished proof  
That the requirements according to

**ISO 9001:2015**

are fulfilled.

The certificate is valid from July 29, 2022 until July 28, 2025  
With a re-issue date on July 11, 2023

Greg Bates  
Director Business Assurance America  
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America

# CERTIFICATE

Certificate Registration No: 951 07 4360

## Certificate Holder:

**Bio-Techne Ltd**  
19 Barton Lane  
Abingdon, OX14 3NB United Kingdom

At the Sites	Specific Scope Site
<b>Bio-Techne Ltd</b> 19 Barton Lane Abingdon, OX14 3NB United Kingdom	Central Functions. Sales, Marketing, Purchasing, Order Processing, Warehousing, Distribution and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne GmbH</b> Borsigstrasse 7A Wiesbaden 65205 Germany	Sales, Marketing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne Ltd</b> Unit F, Heathrow West Business Park Langley, SL3 8XP United Kingdom	Order Processing, Warehousing, and Distribution of Life Science Research Products and Instruments
<b>Bio-Techne SAS</b> 19, Rue Louis Delourmel, CS 49228 Noyal Chatillon Sur Seiche Rennes Cedex 9 35230 France	Virtual site Sales, Marketing, Purchasing, Order Processing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne AG</b> c/o Küng Rechtsanwälte, Poststrasse 13 Zug, 6300 Switzerland	Virtual site Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne R&amp;D Systems s.r.o.</b> Politických vězňů 912/10, Nové Město, Praha 1, 110 00 Czech Republic	Virtual site Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne R&amp;D Systems, s.l.</b> Calle Puerto de Navacerrada, 61 Poligono Las Nieves Mostoles M 28935 Spain	Virtual site Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments

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America

# CERTIFICATE

Certificate Registration No: 951 07 4360

## Certificate Holder:

**Bio-Techne Ltd**  
19 Barton Lane  
Abingdon, OX14 3NB United Kingdom

At the Sites	Specific Scope Site
<b>Bio-Techne R&amp;D Systems Kft.</b> Árpád fejedelem útja 26-28 Budapest, 1023 Hungary	Virtual site Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne sp. z o.o.</b> ul.Towarowa 28 Warsaw, 00-839 Poland	Virtual site Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne Ireland Ltd</b> Unit A6A, North City Business Park North Road, Dublin, D11 Ireland	Sales, Marketing, Order Processing, Warehousing, and Distribution and Customer Service of Life Science Research Products and Instruments
<b>Bio-Techne SAS</b> 2 Chem des Femmes Massy, 91300 France	Sales, Marketing, Order Processing, and Customer Service of Life Science Research Products and Instruments

Greg Bates  
Director Business Assurance America  
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Product Name: CBC-3D<sup>®</sup>

Reviewed on: 15 September 2015

### 1. Identification of Substance:

- **GHS product identifier:** CBC-3D<sup>®</sup>
- **Application of the substance / the preparation:** For in vitro diagnostic use.
- **Manufacturer/Supplier:**  
Bio-techne/R&D Systems<sup>TM</sup>  
614 McKinley Place N.E.  
Minneapolis, MN 55413 USA  
1-800-343-7475
- **For product related questions call:** 1-800-343-7475. In Europe call: +44(0)1235-529449.
- **Emergency information:** In case of a chemical emergency, spill, fire, or exposure, call R&D Systems at (612) 379-2956 or (800)-343-7475. In Europe call +44(0)1235-529449.

### 2. Hazard Identification:

- **Classification:** This substance does not meet the classification criteria to be listed as a hazardous material according to the EC Directives 67/548/EEC, 1999/45/EC, 1272/2008. (EC) No. 1272/2008 [CLP/GHS]:  
Contains Sodium Azide (less than 0.1%) – not a hazardous substance at this concentration.
- **Pictogram:** Not applicable.
- **Signal Word:** Not applicable.
- **Hazard statements:** Not applicable.
- **Precautionary statements:** Not applicable.
- **Response:** Not applicable.
- **Hazard Symbol / R-Phrase / S-Phrase:** Not applicable.
- **Label Elements:** Not applicable.
- **Special Hazards:** Not applicable.

### 3. Information on Ingredients:

- **Contains:** Sodium Azide

Contains	CAS No.	EC-No.	Index-No.	Content
Sodium Azide	26628-22-8	247-852-1	011-004-00-7	<0.1% Not hazardous at this concentration

### 4. First Aid Measures:

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly. Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water. Consult a doctor.
- **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

### 5. Fire Fighting Measures:

- **Suitable extinguishing agents:** Use water spray or extinguishing measure that is appropriate to local circumstances and the surrounding environment.
- **Hazards from the substance or mixture:** Sodium oxides.
- **Special precautions for fire-fighters:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
- **Other information:** This product does not burn.

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bio-techne<sup>®</sup>

bio-techne.com  
info@bio-techne.com  
techsupport@bio-techne.com

North America  
TEL 800 343 7475

Europe • Middle East • Africa  
TEL +44 (0) 1235 529449

China  
info.cn@bio-techne.com  
TEL +86 (21) 52380373

Rest of World  
bio-techne.com/find-us/distributors  
TEL +1 612 379 2956

Bio-Techne is a trading name for R&D Systems

Product Name: CBC-3D<sup>®</sup>

Reviewed on: 15 September 2015

### 6. Accidental Release Measures:

- **Person-related safety precautions:** Use standard laboratory practices and appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.
- **Measures for environmental protection:** Keep away from drains.
- **Measures for containment and cleaning:** Soak up with inert absorbent material and dispose of as per section 13. Keep in suitable, closed containers for disposal.
- **Additional information:** Not available.

### 7. Handling and Storage:

- **Precautions for safe handling:** Avoid inhalation of vapor or mist. Avoid contact with eyes and skin. No special precautions are necessary if used properly.
- **Conditions for safe storage:** Store in a cool, dry place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Do not store in incompatible containers.

### 8. Exposure Controls and Personal Protection:

- **Control parameters:** Not available.
- **Appropriate engineering controls:** Use with adequate ventilation including local extraction. Ensure that eyewash stations and safety showers are close to the workstation location. Follow standard laboratory practices.
- **Individual protection measures:** Wash hands thoroughly after handling chemical products and before eating, smoking or using the restroom. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing.
  - Eye/face protection:** Wear approved safety goggles.
  - Skin/hand protection:** Handle with protective gloves, plastic or rubber. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
  - Body protection:** Wear suitable protective clothing as protection against splashing or contamination.
  - Other skin protection:** Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved.
  - Respiratory protection:** In case of inadequate ventilation, use a suitable respirator. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### 9. Physical and Chemical Properties:

▪ <b>Appearance:</b> Solid or liquid.	▪ <b>Upper/lower flammability or explosive limits:</b> Not available.
▪ <b>Odor:</b> Little to none.	▪ <b>Vapor pressure/density:</b> Not available.
▪ <b>Odor threshold:</b> Not available.	▪ <b>Relative Density:</b> Not available.
▪ <b>pH:</b> Not available.	▪ <b>Solubility in/Miscibility with Water:</b> Not available.
▪ <b>Melting point/freezing point:</b> Not available.	▪ <b>Partition coefficient: n-octanol/water:</b> Not available.
▪ <b>Boiling point/Boiling range:</b> Not available.	▪ <b>Auto igniting:</b> Product is not self-igniting.
▪ <b>Flash point:</b> Not available.	▪ <b>Decomposition temperature:</b> Not available.

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**biotechne**

bio-techne.com  
info@bio-techne.com  
techsupport@bio-techne.com

North America  
TEL 800 343 7475

Europe • Middle East • Africa  
TEL +44 (0) 1235 529449

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Product Name: CBC-3D<sup>®</sup>

Reviewed on: 15 September 2015

▪ <b>Evaporation rate:</b> Not available.	▪ <b>Viscosity:</b> Not available.
▪ <b>Flammability:</b> Not available.	

### 10. Stability and Reactivity:

- **Reactivity:** This product contains low concentrations of Sodium Azide <0.1% (w/w). Sodium Azide can form explosive compounds with heavy metals which, with repeated contact with lead and copper commonly found in plumbing drains may result in the buildup of shock sensitive compounds.
- **Chemical Stability:** Stable under normal ambient and storage and handling temperatures.
- **Thermal decomposition/conditions to be avoided:** No decomposition if used according to specifications.
- **Incompatible materials to be avoided:** Metals and metallic compounds.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11. Toxicological Information:

- **Acute toxicity:** Not available.
- **Skin corrosion/irritation:** Not available.
- **Serious eye damage/irritation:** Not available.
- **Respiratory or skin sensitization:** Not available.
- **Germ cell mutagenicity:** Not available.
- **Carcinogenicity:** IARC: Not available.
- **Reproductive toxicity:** Not available.
- **Specific target organ toxicity (STOT):** Not available.
- **Specific target organ toxicity (STOT) -repeated exposure:** Not available.
- **Aspiration hazard:** Not available.
- **Information on likely routes of exposure:** Routes of entry anticipated; oral, dermal, inhalation.
- **Symptoms related to the physical, chemical and toxicological characteristics:**
  - Inhalation:** Not available.
  - Ingestion:** Not available.
  - Skin contact:** Not available.
  - Eye contact:** Not available.
- **Delayed and immediate effects and also chronic effects from short and long term exposure:**
  - Short term exposure: Potential immediate effects:** Not available. **Potential delayed effects:** Not available.
  - Long term exposure: Potential immediate effects:** Not available. **Potential delayed effects:** Not available.
- **Numerical measures of toxicity:** Not available.
- **Other Information:** Not available.

### 12. Ecological Information:

- **Ecotoxicity:** Not available.
- **Biodegradability:** Not available.
- **Bioaccumulative potential:** Not available.
- **Mobility in soil:** Not available.
- **Other adverse effects:** Not available.

### 13. Disposal Considerations:

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**bio-techne**

bio-techne.com  
info@bio-techne.com  
techsupport@bio-techne.com

North America  
TEL 800 343 7475

Europe • Middle East • Africa  
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- **Disposal methods:** Dispose of waste in accordance to applicable national, regional, or local regulations.
- **Contaminated packaging:** Dispose in the same manner as unused product.
- **Special precautions:** Dispose of small amounts of spilled material as described in section 6. Large spills must be dealt with separately by qualified disposal personnel. Avoid dispersal of spilt material to soil, waterways, drains and sewers.

#### 14. Transportation Information:

- **ADR/RID ADN/ADNR IMDG IATA/DOT:** Not applicable.
- **UN Number:** Not applicable.
- **DOT regulations:** Not applicable.
- **Hazard class:** Not applicable.
- **Land transport ADR/RID (cross-border):** Not applicable.
- **Maritime transport IMDG:** Not applicable.
- **Marine pollutant:** Not applicable.
- **Air transport ICAO-TI and IATA-DGR:** Not applicable.
- **Transport/Additional information:** Not applicable.

#### 15. Regulations:

- **US Federal and State Regulations**
  - TSCA (Toxic Substances Control Act):** Not applicable.
  - SARA 313:** Not applicable.
  - SARA 311/312 Hazards:** Not applicable.
  - CERCLA Reportable Quantity:** Not applicable.
  - California Proposition 65:** WARNING: This product contains a chemical known to the State of California to cause cancer.
- **European Union**
  - This safety datasheet complies with the requirements of Regulation (EC) No. 453/2010.

#### 16. Other Information:

- **Notice to reader:** To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.