



# 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 du 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

## DECLARATION CE DE CONFORMITE DECLARATION OF CE CONFORMITY

**Le produit :**

*The product:*

### CBC-3D

Sang de contrôle multiparamétrique permettant de vérifier l'exactitude et la précision des compteurs d'hématologie.

*Multi-parameter control blood that allows verifying the accuracy and precision of hematology blood cell counters.*

**Fabricant :**

*Manufacturer :*

R&D Systems – a Bio-Techne brand  
614 McKinley Place, N.E.  
MINNEAPOLIS MN 55413  
U.S.A.

**Mandataire :**

*Authorized Representative :*

Bio-Techne  
19 Rue Louis Delourmel  
CS 49228 NOYAL CHATILLON SUR SEICHE  
35092 RENNES CEDEX 9  
FRANCE

**est conforme à l'annexe III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.**

*is in conformity with the annex III of the European Directive 98/79/EC for in vitro diagnostic medical devices.*

Rennes, le 24 Avril 2019

*Rennes April 24<sup>th</sup>, 2019*



Mme BETHUEL Corinne

Directrice Générale

*Manager*

Bio-Techne

Mandataire légal européen des produits d'hématologie R&D Systems.

*European authorized representative of R&D Systems hematology product.*

Product Name: CBC-3D®

Reviewed on: 15 September 2015

### 1. Identification of Substance:

- **GHS product identifier:** CBC-3D®
- **Application of the substance / the preparation:** For in vitro diagnostic use.
- **Manufacturer/Supplier:**  
Bio-techne/R&D Systems™  
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®

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## 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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▪ <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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- **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.