

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

A&T Corporation  
2023-1 Endo  
Fujisawa  
Kanagawa  
252-0816  
Japan

株式会社エイアンドティー  
〒252-0816  
神奈川県  
藤沢市  
遠藤2023番地1

Holds Certificate No: MD 638196

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

1. Design, development, manufacture, distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.
2. Design, development, manufacture and distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)
1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの設計、開発、製造、販売、メンテナンス
2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の設計、開発、製造、販売

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2000-10-20

Latest Revision Date: 2021-10-27

Effective Date: 2021-11-01

Expiry Date: 2024-10-31

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Certificate No: MD 638196

Location

Registered Activities

A&T Corporation  
Shonan Site / Shonan Works  
2023-1 Endo  
Fujisawa  
Kanagawa  
252-0816  
Japan

株式会社エイアンドティー  
湘南サイト/湘南工場  
〒252-0816  
神奈川県  
藤沢市  
遠藤2023番地1

1. Design, development, manufacture and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory), Laboratory Automation System.

2. Maintenance of Laboratory Information System.

3. Design, development, manufacture and distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システムの設計、開発、製造、メンテナンス

2. 臨床検査情報システムのメンテナンス

3. 体外診断用医薬品に使用する（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の設計、開発、製造、販売

A&T Corporation  
Esashi Works  
63-2 Matsunagane, Iwayado, Esashi  
Oshu  
Iwate  
023-1101  
Japan

株式会社エイアンドティー  
江刺工場  
〒023-1101  
岩手県  
奥州市江刺  
岩谷堂字松長根63-2

1. Manufacture of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Manufacture of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの製造

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液）の製造

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Location

Registered Activities

A&T Corporation  
Yokohama Head Office / Shutoken Branch  
Yokohama Plaza Bldg.  
2-6 Kinko-cho  
Kanagawa-ku, Yokohama  
Kanagawa  
221-0056  
Japan  
株式会社エイアンドティー  
横浜本社／首都圏支社  
〒221-0056  
神奈川県  
横浜市神奈川区  
金港町2-6  
横浜プラザビル10階

1. Design, development, distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの設計、開発、販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

A&T Corporation  
Hokkaido Branch  
1F, Nango City House  
3-1 Minami, 13 Nangodori  
Shiraishi-ku, Sapporo  
Hokkaido  
003-0022  
Japan  
株式会社エイアンドティー  
北海道支社  
〒003-0022  
北海道  
札幌市白石区  
南郷通13南3-1  
南郷シティーハウス1F

1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

Original Registration Date: 2000-10-20

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

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Location	Registered Activities
A&T Corporation Tohoku Branch 7F, Sendai Park Bldg. 3-6-1 Kokubun-cho Aoba-ku, Sendai Miyagi 980-0803 Japan 株式会社エイアンドティー 東北支社 〒980-0803 宮城県 仙台市青葉区 国分町3-6-1 仙台パークビル7F	1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System. 2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these) 1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス 2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売
A&T Corporation Kita-Kanto Branch 4F, FSK Bldg. 4-1 Shintoshin Chuo-ku, Saitama-shi Saitama 330-0081 Japan 株式会社エイアンドティー 北関東支社 〒330-0081 埼玉県 さいたま市中央区 新都心4-1 FSKビル 4F	1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System. 2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these) 1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス 2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

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Location

Registered Activities

A&T Corporation  
Chubu Branch  
5F, Pacific Square Nagoyanishiki Bldg.  
2-5-12 Nishiki  
Naka-ku, Nagoya  
Aichi  
460-0003  
Japan  
株式会社エイアンドティー  
中部支社  
〒460-0003  
愛知県  
名古屋市中区  
錦2-5-12  
パシフィックスクエア名古屋錦5F

1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

A&T Corporation  
Kansai Branch  
21F, Osaka Kokusai Bldg.  
2-3-13 Aduchi-machi,  
Chuo-ku, Osaka-shi,  
Osaka  
541-0052  
Japan  
株式会社エイアンドティー  
関西支社  
〒541-0052  
大阪府  
大阪市中央区  
安土町二丁目3番13号  
大阪国際ビルディング21F

1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

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Location

Registered Activities

A&T Corporation  
Chu-shikoku Branch  
11F, Mikawacho Parking Bldg.  
7-7 Mikawa-cho  
Naka-ku, Hiroshima-shi  
Hiroshima  
730-0029  
Japan  
株式会社エイアンドティー  
中四国支社  
〒730-0029  
広島県  
広島市中区  
三川町7-7  
三川町パーキングビル11F

1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

A&T Corporation  
Kyshu Branch  
5F, Fukuoka Tenjin Fukokuseimei Bldg.  
1-9-17 Tenjin  
Chuo-ku, Fukuoka-shi  
Fukuoka  
810-0001  
Japan  
株式会社エイアンドティー  
九州支社  
〒810-0001  
福岡県  
福岡市中央区  
天神1-9-17  
福岡天神フコク生命ビル5F

1. Distribution and maintenance of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment), Laboratory Automation System and Laboratory Information System.

2. Distribution of in-vitro diagnostics reagents (hematology, biochemistry, immunology and control serum, standards, buffer related to these)

1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システム、臨床検査情報システムの販売、メンテナンス

2. 体外診断用医薬品（血液学的検査用試薬、免疫学的検査用試薬、生化学的検査用試薬、その他の管理用血清・標準液・緩衝液）の販売

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Certificate No: MD 638196

Location

Registered Activities

A&T Corporation  
Shonan Site Design Center  
2022-9 Endo,  
Fujisawa,  
Kanagawa  
252-0816  
Japan  
株式会社エイアンドティー  
湘南サイト デザインセンター  
〒252-0816  
神奈川県  
藤沢市  
遠藤2022番地9

1. Design and development of in-vitro diagnostic medical device (Blood test medical device, Urinalysis medical device, Specimen preparatory equipment) Laboratory Automation System.  
1. 体外診断用機器（血液検査用装置、尿検査装置、医用検体前処理装置）、検体検査自動化システムの設計、開発

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