

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

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.

Certificate No: MD 638196

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

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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)

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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)

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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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