



Certificate of Registration

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

This is to certify that: Fukuda Denshi Co., Ltd.
Hongo Head Office
3-39-4 Hongo,
Bunkyo-ku,
Tokyo
113-8483
Japan

フクダ電子株式会社
〒113-8483
東京都
文京区
本郷3-39-4

Holds Certificate No: MD 78466

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

Please see scope page.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-11-03

Latest Revision Date: 2018-09-27

Effective Date: 2018-11-03

Expiry Date: 2021-11-02

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Certificate No: MD 78466

Registered Scope:

The design, development, manufacture, sales, in-house repair, maintenance, storage and distribution of measuring and monitoring equipment for vital signs, electrocardiographs, defibrillators, ultrasound imaging systems, oxygen concentrators and associated accessories.

The design, development, sales, storage and distribution of catheters.

The import, sales, repair (including maintenance and provision of maintenance training), storage and distribution of measuring and monitoring equipment for vital signs, ventilators and associated accessories.

生体信号測定装置、生体信号監視装置、心電計、除細動器、超音波画像診断装置、酸素濃縮装置及びそれらの補用品の設計、開発、製造、販売、修理（保守、保守トレーニングの提供を含む）、保管および出荷
カテーテルの設計、開発、販売、保管及び出荷

生体信号測定装置、生体信号監視装置、人工呼吸器、及びその補用品の輸入、販売、修理（保守、保守トレーニングの提供を含む）、保管及び出荷

Original Registration Date: 2003-11-03

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Expiry Date: 2021-11-02

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone +81 (0)3 6890 1171

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

Fukuda Denshi Co., Ltd.
Hongo Head Office
3-39-4 Hongo,
Bunkyo-ku,
Tokyo
113-8483
Japan
フクダ電子株式会社
〒113-8483
東京都
文京区
本郷3-39-4

The design, development, manufacture, sales, in-house repair, maintenance, storage and distribution of measuring and monitoring equipment for vital signs, electrocardiographs, defibrillators, ultrasound imaging systems, oxygen concentrators and associated accessories. The design, development, sales, storage and distribution of catheters.

The import, sales, repair (including maintenance and provision of maintenance training), storage and distribution of measuring and monitoring equipment for vital signs, ventilators and associated accessories.

Incorporates activities carried out at 2-35-8 and 2-35-27 Hongo

生体信号測定装置、生体信号監視装置、心電計、除細動器、超音波画像診断装置、酸素濃縮装置及びそれらの補用品の設計、開発、製造、販売、修理（保守、保守トレーニングの提供を含む）、保管および出荷

カテーテルの設計、開発、販売、保管及び出荷

生体信号測定装置、生体信号監視装置、人工呼吸器、及びその補用品の輸入、販売、修理（保守、保守トレーニングの提供を含む）、保管及び出荷

その他の活動場所：本郷2-35-8、本郷2-35-27

Fukuda Denshi Co., Ltd.
Shiroi Factory
305-1 Naka,
Shiroi-shi,
Chiba
270-1495
Japan
フクダ電子株式会社
白井事業所
〒270-1495
千葉県
白井市
中305-1

The manufacture of measuring equipment for vital signs and monitoring equipment for vital signs, electrocardiographs, defibrillators, ultrasound imaging systems, oxygen concentrators and associated accessories.

The maintenance of oxygen concentrators.

Import inspection of measuring and monitoring equipment for vital signs, ventilators and associated accessories.

Fukuda Denshi Technical Service Co., Ltd. (A wholly owned subsidiary of Fukuda Denshi Co., Ltd.): In-house repair (including maintenance and provision of maintenance training) of all products.

Fukuda Logistics Center Co., Ltd. (A wholly owned subsidiary of Fukuda Denshi Co., Ltd.): Storage and final staging for distribution.

生体信号測定装置、生体信号監視装置、心電計、除細動器、超音波画像診断装置、酸素濃縮装置、及びそれらの補用品の製造

酸素濃縮器の保守

生体信号測定装置、生体信号監視装置、人工呼吸器、及びその補用品の輸入検査

フクダ電子技術サービス株式会社：認証範囲における全製品の修理（保守、保守トレーニングの提供を含む）

株式会社フクダ物流センター：保管及び出荷

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Location

Registered Activities

Fukuda Denshi Co., Ltd.
Miyuki Business Park No.3,
390 Ichibagi-cho,
Nishi-ku, Nagoya-shi,
Aichi
452-0805
Japan
フクダ電子株式会社
〒452-0805
愛知県
名古屋市西区
市場木町390
ミュキビジネスパーク3号館

The design and development of measuring and monitoring equipment for vital signs and associated accessories.
生体信号測定装置、生体信号監視装置、及びその補用品の設計及び開発

Fukuda Denshi Co., Ltd.
Sumitomo Fudosan Ueno Bldg. No. 2,
2-23-5 Kita Ueno,
Taito-ku,
Tokyo
110-0014
Japan
フクダ電子株式会社
〒110-0014
東京都
台東区
北上野2-23-5
住友不動産上野ビル2号館

Sales of measuring and monitoring equipment for vital signs, electrocardiographs, defibrillators, ultrasound imaging systems, oxygen concentrators, catheters, ventilators and associated accessories.
生体信号測定装置、生体信号監視装置、心電計、除細動器、超音波画像診断装置、酸素濃縮器、カテーテル、人工呼吸器及びそれらの補用品の販売

Fukuda Denshi Co., Ltd.
258 Takedanakajima-cho,
Fushimi-ku, Kyoto-shi,
Kyoto
612-8415
Japan
フクダ電子株式会社
〒612-8415
京都府
京都市伏見区
竹田中島町258番

The design and development of measuring and monitoring equipment for vital signs and associated accessories.
生体信号測定装置、生体信号監視装置、及びその補用品の設計及び開発

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