

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: **NIHON KOHDEN CORPORATION**
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

日本光電工業株式会社
〒161-8560
東京都
新宿区
西落合1-31-4

Holds Certificate No: FM 536761

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Please see scope page.

For and on behalf of BSI:



Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2008-08-24

Latest Revision Date: 2020-03-12

Effective Date: 2018-04-12

Expiry Date: 2021-04-11

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Certificate No: FM 536761

Registered Scope:

Design, development, manufacture and service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, software, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems, patient plates, electrodes and their accessories.

Manufacture (purchasing, inspection, storage) and service provision of imported equipment*

*Imported equipment which is controlled under the Pharmaceutical and Medical Device Act (PMD Act)

電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、外科の用に供する能動な医療機器、リハビリテーションの用に供する能動な医療機器、プログラム、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、医療情報システム、対極板、電極、及びそれらのアクセサリ-の設計・開発、製造及びサービス提供業務

輸入医療機器* の製造（購買、検査、保管）及びサービス提供業務

*輸入医療機器は、薬機法の輸入医療機器を対象とする

Original Registration Date: 2008-08-24

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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: FM 536761

Location

Registered Activities

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
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Japan
日本光電工業株式会社
〒161-8560
東京都
新宿区
西落合1-31-4

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyser.
The purchasing of imported equipment
電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置のサービス提供業務
輸入医療機器の購買

NIHON KOHDEN CORPORATION
Tokorozawa Office
/Advanced Technology Center
1-1-6 Kusunokidai,
Tokorozawa-shi,
Saitama
359-0037
Japan
日本光電工業株式会社
所沢事業所 総合技術開発センタ
〒359-0037
埼玉県
所沢市
くすのき台 1-1-6

Design, development, service provision and order acceptance of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, software, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems, patient plates, electrodes and their accessories.
The purchasing of imported equipment
電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、外科の用に供する能動な医療機器、リハビリテーションの用に供する能動な医療機器、プログラム、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、医療情報システム、対極板、電極及びそれらのアクセサリ設計・開発及びサービス提供、受注輸入医療機器の購買

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Location

Registered Activities

NIHON KOHDEN CORPORATION

Tsurugashima Office
6-2-20 Fujimi,
Tsurugashima-shi,
Saitama
350-2201
Japan
日本光電工業株式会社
鶴ヶ島事業所
〒350-2201
埼玉県
鶴ヶ島市
富士見6-2-20

Storage, and distribution of accessory for defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, and electrodes, probes.

The manufacture (Inspection, storage), and service provision of imported equipment

電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、外科の用に供する能動な医療機器、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置のアクセサリ、及び電極、プローブの保管及び配送

輸入医療機器の製造（検査、保管）及びサービス提供

NIHON KOHDEN CORPORATION

Kawamoto factory
2909-63 Shirokusadai,
Fukaya-shi,
Saitama
369-1106
Japan
日本光電工業株式会社
川本工場
〒369-1106
埼玉県
深谷市
白草台2909-63

Manufacture, Storage and distribution of accessories for non-active non-implantable devices for anaesthesia, emergency and intensive care, non-active instruments, active non-implantable devices for monitoring of vital physiological parameters, and patient plates, electrodes.

Manufacture (labelling), inspection, storage and distribution of lead for intracranial electrodes, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable devices for monitoring of vital physiological parameters.

麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、非能動な器具、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器のアクセサリ、対極板、電極の製造、保管及び配送

電気刺激装置用リード、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器の製造（ラベリング）、検査、保管、配送

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Location

Registered Activities

NIHON KOHDEN CORPORATION

Fujioka Office
1050-3 Nakaotsuka,
Fujioka-shi,
Gunma
375-0053
Japan
日本光電工業株式会社
藤岡事業所
〒375-0053
群馬県
藤岡市
中大塚1050-3

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment
電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、外科の用に供する能動な医療機器、リハビリテーションの用に供する能動な医療機器、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、輸入医療機器のサービス提供業務

NIHON KOHDEN TOMIOKA CORPORATION

Tomiooka Office
486 Nanokaichi,
Tomiooka-shi,
Gunma
370-2343
Japan
日本光電富岡株式会社
富岡事業所
〒370-2343
群馬県
富岡市
七日市486

Manufacture, storage, and distribution of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, software, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems
電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、プログラム、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、医療情報システムの製造、保管及び配送

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Location

Registered Activities

NIHON KOHDEN TOMIOKA CORPORATION

Tomioka Factory II
2027-1 Tomioka,
Tomioka-shi,
Gunma
370-2316
Japan
日本光電富岡株式会社
富岡第2工場
〒370-2316
群馬県
富岡市
富岡 2027-1

Manufacture, storage, and distribution defibrillators, active non-implantable devices for stimulation or inhibition, active non-implantable devices for monitoring of vital physiological parameters and their accessories
電気刺激装置、刺激又は抑制の用に供する能動な医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、及びそれらのアクセサリーの製造、保管及び配送

NIHON KOHDEN TOMIOKA CORPORATION

Tomioka Production Center
1-1 Tajino,
Tomioka-shi,
Gunma
370-2314
Japan
日本光電富岡株式会社
富岡生産センター
〒370-2314
群馬県
富岡市
田篠1-1

Manufacture, storage, and distribution of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, software, active non-implantable imaging devices utilizing non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, healthcare information systems
電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、リハビリテーションの用に供する能動な医療機器、プログラム、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、医療情報システムの製造、保管及び配送

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Location	Registered Activities
NIHON KOHDEN TOMIOKA CORPORATION Advanced Technology Center 1-1-6 Kusunokidai, Tokorozawa-shi, Saitama 359-0037 Japan 日本光電富岡株式会社 総合技術開発センタ 〒359-0037 埼玉県 所沢市 くすのき台1-1-6	Purchasing of components for development and prototype production of medical devices. 医療機器開発及び試作に伴う物品の購買
NIHON KOHDEN TOMIOKA CORPORATION Nihon Kohden Kawamoto Production Center 2909-63 Shirakusadai, Fukaya-shi, Saitama 369-1106 Japan 日本光電富岡株式会社 日本光電 川本生産センタ 〒369-1106 埼玉県 深谷市 白草台2909-63	Manufacture, storage and distribution of accessories for active non-implantable devices for monitoring of vital physiological parameters, and non-active non-implantable devices for anaesthesia, emergency and intensive care, other active non-implantable surgical devices, patient plates, and electrodes. Manufacture (labelling), inspection, storage and distribution of lead for intracranial electrodes, non-active instruments. 生体信号に関わる生理学的指標に係る能動なモニタリング医療機器のアクセサリ、及び麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、外科の用に供する能動な医療機器、対極板、電極の製造、保管及び配送 電気刺激装置用リード、麻酔、非能動な器具の製造（ラベリング）、検査、保管、配送
NIHON KOHDEN TOMIOKA CORPORATION Nihon Kohden Eastern Japan Logistics Center 2-1-1 Nishi Inter, Sakado-shi, Saitama 350-0259 Japan 日本光電富岡株式会社 日本光電 東日本物流センタ 〒350-0259 埼玉県 坂戸市 西インター二丁目1番1	Manufacture (inspection) of active non-implantable devices for monitoring of vital physiological parameters and their accessories. 生体信号に関わる生理学的指標に係る能動なモニタリング医療機器及びそのアクセサリの製造（検査）

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Location

Registered Activities

NIHON KOHDEN CORPORATION
Eastern Japan Logistics Center
2-1-1 Nishi Inter,
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日本光電工業株式会社
東日本物流センター
〒350-0259
埼玉県
坂戸市
西インター二丁目1番1

Storage and distribution of non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, defibrillators, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, software, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, healthcare information systems, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), patient plates, electrodes and their accessories, and imported equipment.

麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、電気刺激装置、外科の用に供する能動な医療機器、リハビリテーションの用に供する能動な医療機器、プログラム、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、医療情報システム、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、対極板、電極、及びそれらのアクセサリ、輸入医療機器の保管、配送

NIHON KOHDEN CORPORATION
Customer Service Operations
Western Japan Service Center
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Suita-shi
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564-0054
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日本光電工業株式会社
カスタマーサービス本部
西日本サービスセンター
〒564-0054
大阪府
吹田市
芳野14-33

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment

電気刺激装置、麻酔、救急及び集中治療の用に供する非能動な非埋植医療機器、呼吸器用の能動な医療機器（酸素療法用の高圧チャンバー及び吸入麻酔用の機器を含む）、刺激又は抑制の用に供する能動な医療機器、非電離放射線を利用する能動な画像医療機器、生体信号に関わる生理学的指標に係る能動なモニタリング医療機器、血液検査装置、輸入医療機器のサービス提供業務

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Location

Registered Activities

NIHON KOHDEN CORPORATION
Customer Service Operations,
AS Hokkaido Division
1-1-14 Minami2johigashi,
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日本光電工業株式会社
カスタマーサービス本部
AS 北海道
〒060-0052
北海道
札幌市中央区
南2条東1-1-14

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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NIHON KOHDEN CORPORATION
Customer Service Operations,
AS Tohoku Division
4-29-7 Izumichuo,
Izumi-ku, Sendai-shi,
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981-3133
Japan
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AS東北
〒981-3133
宮城県
仙台市泉区
泉中央4-29-7

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.

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Certificate No: FM 536761

Location

Registered Activities

NIHON KOHDEN CORPORATION
Customer Service Operations,
AS Higashikanto Division
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AS東関東
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千葉市中央区
末広4-21-21

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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日本光電工業株式会社
カスタマーサービス本部
AS北関東
〒336-0024
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さいたま市南区
根岸3-19-5

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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Location

Registered Activities

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Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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NIHON KOHDEN CORPORATION
Customer Service Operations,
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横浜ビジネスパークノーススクエア1 2F

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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Certificate No: FM 536761

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Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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宮原3-5-36
新大阪トラストタワー6F

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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Location

Registered Activities

NIHON KOHDEN CORPORATION
Customer Service Operations,
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AS 中国
〒733-0002
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広島市西区
楠木町3-15-8

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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カスタマーサービス本部
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〒791-1102
愛媛県
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来住町1439-6

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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Location

NIHON KOHDEN CORPORATION
Customer Service Operations,
AS Kyushu Division
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AS九州
〒812-0007
福岡県
福岡市博多区
東比恵2-12-24

Registered Activities

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, imported equipment (Imported equipment which is controlled under the Pharmaceutical and Medical Device Act, PMD Act)
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