

Certificate of Registration

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

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

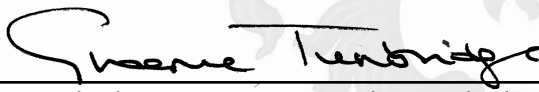
日本光電工業株式会社
〒161-8560
Tokyo
新宿区
西落合1-31-4

Holds Certificate No: MD 536762

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:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2008-08-24

Latest Revision Date: 2024-04-04

Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 1 of 10



...making excellence a habit.™

Certificate No: MD 536762

Registered Scope:

Design, development, manufacture and service provision of defibrillators/electrical stimulator, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices(including Hyperbaric chambers for oxygen therapy and equipment for inhalation anaesthesia), 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, lead for intracranial electrodes, non-active instruments, hearing aid, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices utilising hyperthermia/hypothermia, software, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), patient plates, electrodes.

Design, development of healthcare information systems.

Manufacture and service provision of injection and puncture device, catheter with active function, catheter with non-active function, catheter.

Storage, distribution of probes.

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、電気刺激装置用リード、非能動な器具、補聴器、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、温熱治療又は低体温法の用に供する能動な医療機器、プログラム、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、対極板、電極の設計・開発、製造及びサービス提供業務

医療情報システムの設計開発

注射器具及び穿刺器具、能動機能を有するカテーテル、非能動機能を有するカテーテル、カテーテルの製造及びサービス提供業務

プローブの保管、配送

Original Registration Date: 2008-08-24

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Page: 2 of 10

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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 536762

Location

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
Tokyo
新宿区
西落合1-31-4

Registered Activities

Service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices(including Hyperbaric chambers for oxygen therapy and equipment for inhalation anaesthesia), 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, devices for rehabilitation and devices for patient positioning and transport, active non-implantable devices utilizing hyperthermia/hypothermia, hematology analyser.
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、温熱治療又は低体温法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、血液検査装置のサービス提供業務

Original Registration Date: 2008-08-24

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Page: 3 of 10

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Location

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ー
〒359-0037
埼玉県
所沢市
くすのき台 1-1-6

Registered Activities

Design, development, service provision and order acceptance of electrical stimulator, 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, 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, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems, software, patient plates, electrodes. The import of non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, other active non-implantable surgical devices, hearing aid, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, electrodes.

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、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、医療情報システム、プログラム、対極板、電極の設計・開発及びサービス提供業務、受注麻酔、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）、外科の用に供する能動な医療機器、補聴器、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、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、温熱治療又は低体温法の用に供する能動な医療機器、電極の輸入購買

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Page: 4 of 10

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Location

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

Registered Activities

Lending of active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, devices for rehabilitation and devices for patient positioning and transport, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, and hematology analyzer. Manufacture (labelling), inspection of active non-implantable respiratory devices, other active non-implantable surgical devices, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices for monitoring of vital physiological parameters, and active non-implantable devices utilising hyperthermia/hypothermia. Service provision of active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, devices for rehabilitation and devices for patient positioning and transport, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, and hematology analyzer.

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、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、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、温熱治療又は低体温法の用に供する能動な医療機器、及び血液検査装置の貸出

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）、外科の用に供する能動な医療機器、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、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、及び温熱治療又は低体温法の用に供する能動な医療機器の製造（ラベリング）、検査

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

Original Registration Date: 2008-08-24

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Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 5 of 10

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Location

Registered Activities

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、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、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、温熱治療又は低体温法の用に供する能動な医療機器、及び血液検査装置のサービス提供業務

NIHON KOHDEN CORPORATION

Kawamoto factory
2909-63 Shirakusadai,
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 and storage of non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable devices for monitoring of vital physiological parameters, and patient plates, electrodes. Manufacture (labelling), inspection, and storage of lead for intracranial electrodes, non-active non-implantable devices for anaesthesia, emergency and intensive care, non-active instruments, 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、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、対極板、電極の製造及び保管 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、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製造(ラベリング)、検査及び保管

NIHON KOHDEN TOMIOKA CORPORATION

Tomioka Office
486 Nanokaichi,
Tomioka-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 and storage 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, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c). 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、体外診断用医薬品(ヘモグロビン、CRP、HbA1c)の製造及び保管

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Page: 6 of 10

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Certificate No: MD 536762

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 and storage of active non-implantable devices for stimulation or inhibition, active non-implantable devices for monitoring of vital physiological parameters.
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の製造及び保管

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 and storage 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.
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、血液検査装置の製造及び保管

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ー
〒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

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Expiry Date: 2027-04-05

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Location

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Nihon Kohden Kawamoto Production Center
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Fukaya-shi,
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369-1106
Japan
日本光電富岡株式会社
日本光電 川本生産センター
〒369-1106
埼玉県
深谷市
白草台2909-63

Registered Activities

Manufacture and storage of 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 and storage of lead for intracranial electrodes and 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、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
電気刺激装置用リード及び非能動な器具の製造(ラベリング)、検査及び保管

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Page: 8 of 10

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Location

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2-1-1 Nishi Inter,
Sakado-shi,
Saitama
350-0259
Japan
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

Registered Activities

Storage and distribution of lead for intracranial electrodes, injection and puncture device, catheter with active function, catheter with non-active function, catheter, non-active non-implantable devices for anaesthesia, emergency and intensive care, non-active instruments, active non-implantable respiratory devices(including Hyperbaric chambers for oxygen therapy and equipment for inhalation anaesthesia), 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, hearing aid, active non-implantable imaging devices utilising non-ionizing radiation, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, hematology analyzer, software, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), patient plates, electrodes, probes.

電気刺激装置用リード、注射器具及び穿刺器具、能動機能を有するカテーテル、非能動機能を有するカテーテル、カテーテル、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、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、補聴器、非電離放射線を利用する能動な画像医療機器、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、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、温熱治療又は低体温法の用に供する能動な医療機器、血液検査装置、プログラム、体外診断用医薬品（ヘモグロビン、CRP、HbA1c）、対極板、電極、プローブの保管、配送

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Page: 9 of 10

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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 536762

Location

Registered Activities

NIHON KOHDEN CORPORATION
Customer Service Operations
Western Japan Service Center
14-33, Yoshino-cho,
Suita-shi
Osaka
564-0054
Japan
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
芳野町14-33

Service provision of active non-implantable respiratory devices(including Hyperbaric chambers for oxygen therapy and equipment for inhalation anaesthesia), 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.
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

NIHON KOHDEN CORPORATION
Eastern Japan Logistics Center
(Manufacture)
2-1-1 Nishi Inter,
Sakado-shi,
Saitama
350-0259
Japan
日本光電株式会社
東日本物流センター（製造）
〒350-0259
埼玉県
坂戸市
西インター二丁目1番1

Manufacture (labelling), inspection of non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for monitoring of vital physiological parameters, injection and puncture device, catheter with active function, catheter with non-active function, catheter, hearing aid, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices utilising hyperthermia /hypothermia, electrodes.
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）、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、注射器具及び穿刺器具、能動機能を有するカテーテル、非能動機能を有するカテーテル、カテーテル、補聴器、生体信号に関わらない生理学的指標に係る能動なモニタリング医療機器、温熱治療又は低体温法の用に供する能動な医療機器、電極の製造（ラベリング）、検査

Original Registration Date: 2008-08-24

Effective Date: 2024-04-06

Latest Revision Date: 2024-04-04

Expiry Date: 2027-04-05

Page: 10 of 10

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