

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - 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
東京都
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 for the following scope:

Please see scope page.

For and on behalf of BSI:



Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 2008/08/24

Latest Revision Date: 2017/02/09

Effective Date: 2017/01/19

Expiry Date: 2020/01/18

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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

Registered Scope:

Design, development, manufacture and service provision of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, endoscopes, hematology analyzer, specific protein analyzer (CRP, HbA1c), electrosurgical patient plates, medical electronic stimulator, rhinorheograph and in vitro diagnostic reagents(hemoglobin, CRP, HbA1c), healthcare information systems

Purchasing, manufacture (labeling), inspection, storage and service provision of cardiac pacemakers, catheters, lung ventilators, anesthesia apparatus, warming devices, pulmonary function testing devices, electroencephalographs, evoked potential measuring systems, cardiac output monitors, infusion instruments and splints

生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、内視鏡、血液検査装置、蛋白分析装置(CRP、HbA1c)、対極板、医療用電気刺激装置、鼻腔通気度計、体外診断薬(ヘモグロビン、CRP、HbA1c)、医療情報システムの設計・開発、製造及びサービス提供業務
心臓ペースメーカー、カテーテル、人工呼吸器、麻酔器、加温装置、肺機能検査装置、脳波計、誘発電位検査装置、心拍出量計、医薬品注入器、副木の購買、製造(ラベリング)、検査、保管及びサービス提供業務

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Location

Registered Activities

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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

Design, development, and service provision of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs<(>,<)> evoked potential measuring systems, endoscopes, hematology analyzer, specific protein analyzer (CRP, HbA1c), electrosurgical patient plates, medical electronic stimulator, rhinorheograph, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems
The import of lung ventilators, anesthesia apparatus and warming devices
生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、内視鏡、血液検査装置、蛋白分析装置(CRP、HbA1c)、対極板、医療用電気刺激装置、鼻腔通気度計、体外診断薬(ヘモグロビン、CRP、HbA1c)、医療情報システムの設計・開発、及びサービス提供
人工呼吸器、麻酔器、加温装置の輸入購買

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, and service provision of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, endoscopes, hematology analyzer, specific protein analyzer (CRP, HbA1c), electrosurgical patient plates, medical electronic stimulator, rhinorheograph, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems
The import of lung ventilators, anesthesia apparatus and warming devices
生体情報モニタ、医療用CO2
モニタ、パルスオキシメータ、
心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、内視鏡、血液検査装置、蛋白分析装置(CRP、HbA1c)、対極板、医療用電気刺激装置、鼻腔通気度計、体外診断薬(ヘモグロビン、CRP、HbA1c)、医療情報システムの設計・開発、及びサービス提供
人工呼吸器、麻酔器、加温装置の輸入購買

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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	Order acceptance, storage, and distribution of accessory for patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterization systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, endoscopes, hematology analyzer, specific protein analyzer (CRP, HbA1c), electrosurgical patient plates, medical electronic stimulator, rhinorheograph, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c) Manufacture (labelling), inspection, storage, distribution, and service provision of cardiac pacemakers, catheters, lung ventilators, anesthesia apparatus, warming devices, pulmonary function testing devices, electroencephalographs, evoked potential measuring systems, cardiac output monitors, infusion instruments, splints Manufacture and service provision of healthcare information systems 生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、内視鏡、血液検査装置、蛋白分析装置(CRP、HbA1c)、対極板、医療用電気刺激装置、鼻腔通気度計、体外診断薬(ヘモグロビン、CRP、HbA1c)のアクセサリーの受注、保管及び配送 心臓ペースメーカー、カテーテル、人工呼吸器、麻酔器、加温装置、肺機能検査装置、脳波計(輸入)、誘発電位検査装置(輸入)、心拍出量計、医薬品注入器、副木の製造(ラベリング)、検査、保管、配送及びサービス提供 医療情報システムの製造及びサービス提供業務
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	Design, development, and manufacture of accessory for patient monitoring systems, CO2 monitors for medical application, pulse oximeters, defibrillators, electrocardiographs, electroencephalographs, evoked potential measuring systems, endoscopes, electrosurgical patient plates, medical electronic stimulator, rhinorheograph 生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、デフィブリレータ、心電計、脳波計、誘発電位検査装置、内視鏡、対極板、医療用電気刺激装置、鼻腔通気度計のアクセサリーの設計・開発及び製造

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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, storage, and distribution of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, hematology analyzer, specific protein analyzer (CRP, HbA1c), medical electronic stimulator, rhinorheograph, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c) 生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、血液検査装置、蛋白分析装置 (CRP、HbA1c)、医療用電気刺激装置、鼻腔通気度計、体外診断薬(ヘモグロビン、CRP、HbA1c)の製造、保管及び配送
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 of defibrillators デフィブリレータの製造、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 〒370-2314 群馬県 富岡市 田篠1-1	Manufacture, storage, and distribution of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, hematology analyzer, specific protein analyzer (CRP, HbA1c), medical electronic stimulator, rhinorheograph 生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、血液検査装置、蛋白分析装置 (CRP、HbA1c)、医療用電気刺激装置、鼻腔通気度計の製造、保管及び配送

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NIHON KOHDEN TOMIOKA CORPORATION Tokyo Office 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560 Japan 日本光電富岡株式会社 東京事業所 〒161-8560 東京都 新宿区 西落合1-31-4	Purchasing of patient monitoring systems, CO2 monitors for medical application, pulse oximeters, cardiac catheterisation systems, defibrillators, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs, evoked potential measuring systems, endoscopes, hematology analyzer, specific protein analyzer (CRP, HbA1c), electrosurgical patient plates, medical electronic stimulator, rhinorheograph, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems 生体情報モニタ、医療用CO2 モニタ、パルスオキシメータ、心臓カテーテル検査装置、デフィブリレータ、心電計、長時間心電図解析システム、脳波計、誘発電位検査装置、内視鏡、血液検査装置、蛋白分析装置 (CRP、HbA1c)、対極板、医療用電気刺激装置、鼻腔通気度計、体外診断薬 (ヘモグロビン、CRP、HbA1c)、医療情報システムの購買
NIHON KOHDEN TOMIOKA CORPORATION Tsurugashima Office 6-2-20 Fujimi, Tsurugashima-shi, Saitama 350-2201 Japan 日本光電富岡株式会社 鶴ヶ島事業所 〒350-2201 埼玉県 鶴ヶ島市 富士見6-2-20	Manufacture of healthcare information systems 医療情報システムの製造
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 of accessory for patient monitoring systems, CO2 monitors for medical application, pulse oximeters, defibrillators, electrocardiographs, electroencephalographs, evoked potential measuring systems, endoscopes, electrosurgical patient plates, medical electronic stimulator, rhinorheograph 生体情報モニタ、医療用CO2モニタ、パルスオキシメータ、デフィブリレータ、心電計、脳波計、誘発電位検査装置、内視鏡、対極板、医療用電気刺激装置、鼻腔通気度計のアクセサリーの製造

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