



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

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: 2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

President, Mitsunasa Tokunaga

Originally registered: **2008/08/24**

Latest Issue: **2008/08/24**

Expiry Date: **2011/05/19**



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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.bsi-global.com/ClientDirectory or telephone +81(0)3 5501 7121. Further clarifications regarding the scope of this certificate and the applicability of ISO 13485: 2003 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Japan Headquarters: Toranomon Kotohira Tower 21F, 1-2-8 Toranomon Minato-ku Tokyo 105-0001, Japan.
BSI Management Systems Japan K.K.



Certificate No: **MD 536762**

Registered Scope:

The design, development, manufacture and service provision of the following equipment*
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, electrosurgical patient plates, in vitro diagnostic reagents

*Except imported equipment

次の製品*の設計・開発、製造及びサービス提供業務

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、対極板、体外診断薬

* 但し、輸入医療機器を除く

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Location

Registered Activities

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

Design, development and service provision
設計・開発及びサービス提供

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
購買

Nihon Kohden Corporation
Higashinakano Office
3-14-20 Higashinakano,
Nakano-ku,
Tokyo
164-0003
Japan
日本光電工業株式会社
東中野事業所
〒164-0003
東京都
中野区
東中野3-14-20

Order acceptance
受注

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BSI Management Systems Japan K.K.

Certificate No: **MD 536762**

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

Order acceptance, storage, distribution
受注、保管及び配送

Nihon Kohden Corporation
Kawamoto factor
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
設計・開発及び製造

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
製造、保管及び配送

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