

# 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

Facility ID Number: F000334

Holds Certificate No:

**MDSAP 680668**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-15

Effective Date: 2024-04-06

Expiry Date: 2027-04-05



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 5

...making excellence a habit.™

Certificate No: **MDSAP 680668**

## Registered Scope:

Design, development, manufacture and servicing of defibrillators/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, 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.

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

Design, development of healthcare information systems.



Original Registration Date: 2018-10-15      Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 2 of 5

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 680668**

Location	Registered Activities
NIHON KOHDEN CORPORATION 1-31-4 Nishiochiai Shinjuku-ku Tokyo 161-8560 Japan Facility ID Number: F000334	Service of defibrillator, 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 nonionizing 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 utilising hyperthermia/hypothermia, hematology analyser.
NIHON KOHDEN CORPORATION Tsurugashima Office 6-2-20 Fujimi, Tsurugashima-shi, Saitama 350-2201 Japan Facility ID Number: F001913	<p>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 nonionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, and hematology analyzer.</p> <p>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.</p> <p>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 nonionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, active non-implantable devices utilising hyperthermia/hypothermia, and hematology analyzer.</p>

Original Registration Date: 2018-10-15

Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 3 of 5

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 680668**

Location	Registered Activities
<p>NIHON KOHDEN CORPORATION Kawamoto factory 2909-63 Shirakusadai, Fukaya-shi, Saitama 369-1106 Japan Facility ID Number: F001916</p>	<p>Manufacture of nonactive non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable devices for monitoring of vital physiological parameters, patient plates and electrodes.</p> <p>Manufacture (labelling) and inspection 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.</p>
<p>NIHON KOHDEN TOMIOKA CORPORATION Tomioka Office 486 Nanokaichi, Tomioka-shi, Gunma 370-2343 Japan Facility ID Number: F001915</p>	<p>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).</p>
<p>NIHON KOHDEN TOMIOKA CORPORATION Tomioka Factory II 2027-1 Tomioka, Tomioka-shi, Gunma 370-2316 Japan Facility ID Number: F001915</p>	<p>Manufacture and storage of active non-implantable devices for stimulation or inhibition and active non-implantable devices for monitoring of vital physiological parameters.</p>
<p>NIHON KOHDEN TOMIOKA CORPORATION Tomioka Production Center 1-1 Tajino, Tomioka-shi, Gunma 370-2314 Japan Facility ID Number: F001915</p>	<p>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 analyser.</p>

Original Registration Date: 2018-10-15      Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 4 of 5

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 680668**

Location	Registered Activities
<p>NIHON KOHDEN CORPORATION Tokorozawa Office /Advanced Technology Center 1-1-6 Kusunokidai, Tokorozawa-shi, Saitama 359-0037 Japan Facility ID Number: F001914</p>	<p>Design, development, service provision and order acceptance of electrical stimulator, nonactive 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.</p> <p>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.</p>
<p>NIHON KOHDEN TOMIOKA CORPORATION Nihon Kohden Kawamoto Production Center 2909-63 Shirakusadai, Fukaya-shi, Saitama 369-1106 Japan Facility ID Number: F001916</p>	<p>Manufacture 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.</p> <p>Manufacture (labelling) and inspection of lead for intracranial electrodes and non-active instruments.</p>
<p>NIHON KOHDEN CORPORATION Eastern Japan Logistics Center (Manufacture) 2-1-1 Nishi Inter, Sakado-shi, Saitama 350-0259 Japan Facility ID Number: F005886</p>	<p>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.</p>

Original Registration Date: 2018-10-15

Effective Date: 2024-04-06

Expiry Date: 2027-04-05

Page: 5 of 5

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.