

Certification

Awarded to

HEARMEC CO., LTD.

956-2, YURA-CHO, OTA-SHI, GUNMA 373-0036, JAPAN

This is a multi-site certificate. Additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below.

STANDARD

ISO 13485:2003

SCOPE OF SUPPLY

**DESIGN, DEVELOPMENT, MANUFACTURING, SALES AND
INSTALLATION OF HYPERBARIC OXYGEN CAPSULE.
IMPORT, MANUFACTURING, PACKAGING, STORAGE AND SALES
OF DRY HOT PACK MEDICAL EQUIPMENT.
MAINTENANCE REPAIR OF MEDICAL EQUIPMENT FOR
PHYSIOTHERAPY.**

Original approval date: 12-03-2013

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: 28-02-2019

To check the validity of this certificate, please call: (+45) 77 311 000.

Further clarification regarding the scope of this certificate and the applicability of the system requirements may be obtained by consulting the organisation

Certificate Number: DNKFRC100314AA Date: 03-03-2016



Certification office: Bureau Veritas Certification Denmark A/S
Oldenborggade 1B, 7000 Fredericia, Denmark
E-mail: medicaldkmail@dk.bureauveritas.com
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Naka-ku, Yokohama, 231-0023 Japan

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DANAK
SYSTEM Reg nr. 5005





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Standard

ISO 13485:2003

Bureau Veritas Certification has issued this appendix to the certificate of approval of the above organisation.

Head Quarter: 956-2, YURA-CHO, OTA-SHI, GUNMA 373-0036, JAPAN

Sites:

Sites:	Address:	Scope:
HEAD QUARTER	956-2, YURA-CHO, OTA-SHI, GUNMA 373-0036, JAPAN	<ul style="list-style-type: none">• SALES AND INSTALLATION OF HYPERBARIC OXYGEN CAPSULE.• IMPORT AND SALES OF DRY HOTPACK MEDICAL EQUIPMENT.• MAINTENANCE REPAIR OF MEDICAL EQUIPMENT FOR PHYSIOTHERAPY.
TORIYAMA FACTORY	1572, TORIYAMAKAMI-CHO, OTA-SHI, GUNMA 373-0061, JAPAN	<ul style="list-style-type: none">• DESIGN, DEVELOPMENT, MANUFACTURING OF HYPERBARIC OXYGEN CAPSULE.• MANUFACTURING, PACKAGING AND STORAGE OF DRY HOTPACK MEDICAL EQUIPMENT• MAINTENANCE REPAIR OF MEDICAL EQUIPMENT FOR PHYSIOTHERAPY.

Certificate Number: DNKFRC100314AA

Date: 03-03-2016

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SYSTEM Reg.nr. 5005

