QUALITY SYSTEM CERTIFICATE

This is to Certify that the Quality Management System of

SALINEE HEALTHCARE SDN. BHD. (542382-W)

697, Jalan Duku,
Taman Duku, Juru,
14100 Penang,
Malaysia

has been assessed by KGS Certification Sdn. Bhd.
and found to comply with

ISO 13485:2016
Medical Devices Quality Management System

for the scope

Design, Manufacture, Installation and Servicing of Health Care Automation Software and Solutions

Certificate No	:	**510162**
Date of Initial Certification	:	**24 January 2018**
Date of Issue/Reissue	:	**24 January 2018**
Renewal Due	:	**23 January 2021**

STANDARDS MALAYSIA ACCREDITED CERTIFICATION BODY

MDQMS 15102014 CB 01

Authorized Signatory

This certificate is subject to the company maintaining its system to the required standards, which will be monitored by KGS. The use of this Certificate and the KGS Certification / Accreditation Mark are subject to the Regulations Applicable to Holders of KGS Certification Sdn. Bhd.

KGS Certification Sdn. Bhd. (824092-A)
No. 15, BLM 5/4, Laguna Merbok, 08000 Sungai Petani, Kedah Darul Aman, Malaysia.
Tel: 604 441 1524 Fax: 604 441 0610 Email: kgscertification@gmail.com
www.kgscert.com

No. Siri: 001855
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen: *License No.:*	**KP65954155116**	Tarikh Sah Lesen: *License Validity Date:*	**11/10/2016** **10/10/2019**

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

SALINEE HEALTHCARE SDN BHD

yang beralamat di:
of

SALINEE HEALTHCARE SDN BHD
D-3-2, BLOCK D, MEGAN AVENUE 1
NO 189, JALAN TUN RAZAK,
50400 KUALA LUMPUR

Sebagai:
as

WAKIL DIBERI KUASA, PENGIMPORT, PENGEDAR
AUTHORIZED REPRESENTATIVE, IMPORTER, DISTRIBUTOR

Orang yang bertanggungjawab: **RAMASAMY A/L KANDASAMY (I/C: 490104-07-5459)**
Person Responsible:

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

No. Siri: 002568
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen: *License No.:*	**KP19139191418**	Tarikh Sah Lesen: *License Validity Date:*	**28/02/2018** **27/02/2021**

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

SALINEE HEALTHCARE SDN BHD

yang beralamat di:
of
NO 697 JALAN DUKU, TAMAN DUKU
14100 SIMPANG AMPAT, JURU
14100 PULAU PINANG

Sebagai:
as
PEMBUAT
MANUFACTURER

Orang yang bertanggungjawab: **DATO DR.RAMASAMY A/L KANDASAMY (I/C: 490104-07-5459)**
Person Responsible:

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

SALINEE HEALTHCARE SDN BHD
697, Jalan Duku, Taman Duku
Juru 14100 Pulau Pinang
MALAYSIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated May 07, 2018

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2018-05-07

Elsa Villanueva-Möller

Elsa Villanueva-Möller
Director of Administration / Business Development
MDSS GmbH