No. Siri: 004616
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 24(1) Akta 737
Section 24(1) of Act 737

No. Lesen: **MDA-1044-WDP8116**
Licence No.:

Tarikh Sah Lesen: **04/01/2019 - 03/01/2022**
Licence Validity Date:

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

SURGICAL SOLUTIONS (M) SDN. BHD.

yang beralamat di:
of

10-8-6, QUEENS AVENUE,
JALAN BAYAM,
55100 KUALA LUMPUR

Sebagai:
as

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

Orang yang bertanggungjawab:
Person Responsible

MERVIN PAUL RAMACHANDRAN (I/C NO. : 630615-10-7477)

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.

AHMAD SHARIFF BIN HAMBALI
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

No. Siri: 020405
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)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GB69022973118**
Registration No.:

Tarikh Sah Laku Pendaftaran: **01/06/2018 - 31/05/2023**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

SURGICAL SOLUTIONS (M) SDN. BHD.

yang beralamat di:
of:

10-8-6 QUEENS AVENUE
JALAN BAYAM
55100 KUALA LUMPUR

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

Ref: (74) MDA.600-1/6/20 JLD 31
Date: 26 February 2020

Attachment 1

No	Name Of Device, Constituent Components, Accessories, Reagents Or Articles As Per Product Label	Device Identifier	Brief Description Of Item
1	Glustitch - Topical Tissue Adhesive 1ml	GLUST-1(V)	20 Pipettes + 20 Dishes + 1 T-Seal Pin For Multiuse - Good for 20 Uses / Applications
2	Glustitch - Topical Tissue Adhesive 0.2ml	GLUST-U(V)ST	For Single Use (Pack for 10 Uses / Applications)
3	Glustitch Twist Tissue Adhesive 0.5ml	GLTWI05CECL	For Single Use (Pack for 6 Uses / Applications)
4	Glustitch - Topical Tissue Adhesive 0.2ml	GLUST-U(V)ST	For Single Use (Pack for 5 Uses / Applications)

No. Siri:
Serial No.: **035386**

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)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GA2316620-43993**
Registration No.:

Tarikh Sah Laku Pendaftaran: **22/06/2020 - 21/06/2025**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **SURGICAL SOLUTIONS (M) SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di: **10-8-6 QUEENS AVENUE JALAN BAYAM , 55100 KUALA LUMPUR**
which is located at:

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GA2316620-43993**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**PERIACRYL 90HV**		
Kelas *Class*	**CLASS A**	Jenama *Brand*	**GLUSTITCH**
Kelompok *Group*	**FAMILY**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**GLUSTITCH INC.** **307-7188 PROGRESS WAY DELTA,BRITISH COLUMBIA V4G 1M6, CANADA** **V4G 1M6,** **CANADA**		

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	PeriAcryl®90 High Viscosity - Oral Tissue Adhesive 2ml	P-ACRYL2(V)CEHV	20 Pipettes + 1 Autoclavable Tray Good for 20 Uses / Applications
2	PeriAcryl®90 High Viscosity - Oral Tissue Adhesive 0.2ml	P-ACRYLU(V)HVCE	1) For Single Use (Pack for 10 Uses / Applications) 2) For Single Use (Pack for 5 Uses / Applications) 3) For Single Use (Pack for 2 Uses / Applications)
"End Of Product List"			

No. Siri:
Serial No.: **033937**

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)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GD9900520-40620**
Registration No.:

Tarikh Sah Pendaftaran: **04/03/2020 - 03/03/2025**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **SURGICAL SOLUTIONS (M) SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:
10-8-6 QUEENS AVENUE JALAN BAYAM ,
55100
KUALA LUMPUR

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GD9900520-40620**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **STARSIL® HEMOSTAT**
Medical Device Name

Kelas **CLASS D** Jenama **HEMOSTAT**
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **HEMOSTAT MANUFACTURING GMBH BECKELMANNSWEG 10, D-46342 VELEN GERMANY, D-46342 GERMANY**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	STARSIL®HEMOSTAT 1g	SS 001	SS001 contains 1 g substance
2	STARSIL®HEMOSTAT 2g	SS 002	SS002 contains 2 g substance
3	STARSIL®HEMOSTAT 3g	SS 003	SS003 contains 3 g substance
4	STARSIL®HEMOSTAT 5g	SS 005	SS005 contains 5 g substance
"End Of Product List"			