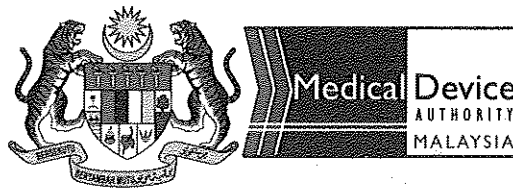


ASAL  
ORIGINAL

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: **GC5565720-44511**  
Registration No.:

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

Sijil ini adalah dengan ini diberi kepada:  
*This certificate is hereby issued to:*

**JOINT IMPLANT SYSTEMS SDN BHD**

yang beralamat di:  
*which is located at:*

**NO 12, JALAN INDUSTRI PBP 12 TAMAN  
INDUSTRI PUSAT BANDAR PUCHONG  
PUCHONG,  
47100  
SELANGOR DARUL EHSAN**

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



No. Pendaftaran: **GC5565720-44511**  
Registration No.:

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

Nama Peranti Perubatan **STEMSYS FEMORAL STEM AND HEADS**  
Medical Device Name

Kelas **CLASS C** Jenama **STEMSYS**  
Class Brand

Kelompok **FAMILY**  
Group

Nama dan alamat pembuat: **EVOLUTIS SAS**  
Name and address of manufacturer **AVENUE DE LA LIBERATION BRIENNON,**  
**42720**  
**FRANCE**

**Medical Device** **APPENDIX**

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Stemsys Standard Cemented Stem Size 9	H45 S009	Standard Cemented Mirror Polished Stem
2	Stemsys Standard Cemented Stem Size 10	H45 S010	Standard Cemented Mirror Polished Stem
3	Stemsys Standard Cemented Stem Size 11	H45 S011	Standard Cemented Mirror Polished Stem
4	Stemsys Standard Cemented Stem Size 12	H45 S012	Standard Cemented Mirror Polished Stem
5	Stemsys Standard Cemented Stem Size 13	H45 S013	Standard Cemented Mirror Polished Stem
6	Stemsys Standard Cemented Stem Size 14	H45 S014	Standard Cemented Mirror Polished Stem
7	Stemsys Standard Cemented Stem Size 15	H45 S015	Standard Cemented Mirror Polished Stem
8	Stemsys Standard Cemented Stem Size 16	H45 S016	Standard Cemented Mirror Polished Stem
9	Stemsys Standard Cemented Stem Size 18	H45 S018	Standard Cemented Mirror Polished Stem
10	Stemsys Lateralised Cemented Stem Size 9	H45 SL09	Lateralised Cemented Mirror Polished Stem
11	Stemsys Lateralised Cemented Stem Size 10	H45 SL10	Lateralised Cemented Mirror Polished Stem



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
12	Stemsys Lateralised Cemented Stem Size 11	H45 SL11	Lateralised Cemented Mirror Polished Stem
13	Stemsys Lateralised Cemented Stem Size 12	H45 SL12	Lateralised Cemented Mirror Polished Stem
14	Stemsys Lateralised Cemented Stem Size 13	H45 SL13	Lateralised Cemented Mirror Polished Stem
15	Stemsys Lateralised Cemented Stem Size 14	H45 SL14	Lateralised Cemented Mirror Polished Stem
16	Stemsys Lateralised Cemented Stem Size 15	H45 SL15	Lateralised Cemented Mirror Polished Stem
17	Stemsys Lateralised Cemented Stem Size 16	H45 SL16	Lateralised Cemented Mirror Polished Stem
18	Stemsys Standard Cementless Stem Size 7	H45 007	Standard Cementless Stem Titanium & HA Coated
19	Stemsys Standard Cementless Stem Size 8	H45 008	Standard Cementless Stem Titanium & HA Coated
20	Stemsys Standard Cementless Stem Size 9	H45 009	Standard Cementless Stem Titanium & HA Coated
21	Stemsys Standard Cementless Stem Size 10	H45 0010	Standard Cementless Stem Titanium & HA Coated
22	Stemsys Standard Cementless Stem Size 11	H45 0011	Standard Cementless Stem Titanium & HA Coated
23	Stemsys Standard Cementless Stem Size 12	H45 0012	Standard Cementless Stem Titanium & HA Coated
24	Stemsys Standard Cementless Stem Size 13	H45 0013	Standard Cementless Stem Titanium & HA Coated
25	Stemsys Standard Cementless Stem Size 14	H45 0014	Standard Cementless Stem Titanium & HA Coated
26	Stemsys Standard Cementless Stem Size 15	H45 0015	Standard Cementless Stem Titanium & HA Coated
27	Stemsys Standard Cementless Stem Size 16	H45 0016	Standard Cementless Stem Titanium & HA Coated
28	Stemsys Standard Cementless Stem Size 18	H45 0018	Standard Cementless Stem Titanium & HA Coated
29	Stemsys Standard Cementless Stem Size 20	H45 0020	Standard Cementless Stem Titanium & HA Coated
30	Stemsys Standard&Collared Cementless Stem Size 8	H45 C008	Standard&Collared Cementless Stem Titanium & HA Coated
31	Stemsys Standard&Collared Cementless Stem Size 9	H45 C009	Standard&Collared Cementless Stem Titanium & HA Coated



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
32	Stemsys Standard&Collared Cementless Stem Size 10	H45 C0010	Standard&Collared Cementless Stem Titanium & HA Coated
33	Stemsys Standard&Collared Cementless Stem Size 11	H45 C0011	Standard&Collared Cementless Stem Titanium & HA Coated
34	Stemsys Standard&Collared Cementless Stem Size 12	H45 C0012	Standard&Collared Cementless Stem Titanium & HA Coated
35	Stemsys Standard&Collared Cementless Stem Size 13	H45 C0013	Standard&Collared Cementless Stem Titanium & HA Coated
36	Stemsys Standard&Collared Cementless Stem Size 14	H45 C0014	Standard&Collared Cementless Stem Titanium & HA Coated
37	Stemsys Standard&Collared Cementless Stem Size 15	H45 C0015	Standard&Collared Cementless Stem Titanium & HA Coated
38	Stemsys Standard&Collared Cementless Stem Size 16	H45 C0016	Standard&Collared Cementless Stem Titanium & HA Coated
39	Stemsys Standard&Collared Cementless Stem Size 18	H45 C0018	Standard&Collared Cementless Stem Titanium & HA Coated
40	Stemsys Lateralised Cementless Stem Size 9	H45 L009	Lateralised Cementless Stem Titanium & HA Coated
41	Stemsys Lateralised Cementless Stem Size 10	H45 L0010	Lateralised Cementless Stem Titanium & HA Coated
42	Stemsys Lateralised Cementless Stem Size 11	H45 L0011	Lateralised Cementless Stem Titanium & HA Coated
43	Stemsys Lateralised Cementless Stem Size 12	H45 L0012	Lateralised Cementless Stem Titanium & HA Coated
44	Stemsys Lateralised Cementless Stem Size 13	H45 L0013	Lateralised Cementless Stem Titanium & HA Coated
45	Stemsys Lateralised Cementless Stem Size 14	H45 L0014	Lateralised Cementless Stem Titanium & HA Coated
46	Stemsys Lateralised Cementless Stem Size 15	H45 L0015	Lateralised Cementless Stem Titanium & HA Coated
47	Stemsys Lateralised Cementless Stem Size 16	H45 L0016	Lateralised Cementless Stem Titanium & HA Coated
48	Stemsys Lateralised Cementless Stem Size 18	H45 L0018	Lateralised Cementless Stem Titanium & HA Coated
49	Stemsys Lateralised Cementless Stem Size 20	H45 L0020	Lateralised Cementless Stem Titanium & HA Coated
50	Stemsys Lateralised&Collared Cementless Stem Size 9	H45 LC009	Lateralised&Collared Cementless Stem Titanium & HA Coated
51	Stemsys Lateralised&Collared Cementless Stem Size 10	H45 LC0010	Lateralised&Collared Cementless Stem Titanium & HA Coated



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
52	Stemsys Lateralised&Collared Cementless Stem Size 11	H45 LC0011	Lateralised&Collared Cementles Stem Titanium & HA Coated
53	Stemsys Lateralised&Collared Cementless Stem Size 12	H45 LC0012	Lateralised&Collared Cementles Stem Titanium & HA Coated
54	Stemsys Lateralised&Collared Cementless Stem Size 13	H45 LC0013	Lateralised&Collared Cementles Stem Titanium & HA Coated
55	Stemsys Lateralised&Collared Cementless Stem Size 14	H45 LC0014	Lateralised&Collared Cementles Stem Titanium & HA Coated
56	Stemsys Lateralised&Collared Cementless Stem Size 15	H45 LC0015	Lateralised&Collared Cementles Stem Titanium & HA Coated
57	Stemsys Lateralised&Collared Cementless Stem Size 16	H45 LC0016	Lateralised&Collared Cementles Stem Titanium & HA Coated
58	Stemsys Lateralised&Collared Cementless Stem Size 18	H45 LC0018	Lateralised&Collared Cementles Stem Titanium & HA Coated
59	Stemsys Lateralised&Collared Cementless Stem Size 20	H45 LC0020	Lateralised&Collared Cementles Stem Titanium & HA Coated
60	Stemsys Standard Cementless Stem Size 7	H73 007	Standard Cementles Stem HA Coated
61	Stemsys Standard Cementless Stem Size 8	H73 008	Standard Cementles Stem HA Coated
62	Stemsys Standard Cementless Stem Size 9	H73 009	Standard Cementles Stem HA Coated
63	Stemsys Standard Cementless Stem Size 10	H73 0010	Standard Cementles Stem HA Coated
64	Stemsys Standard Cementless Stem Size 11	H73 0011	Standard Cementles Stem HA Coated
65	Stemsys Standard Cementless Stem Size 12	H73 0012	Standard Cementles Stem HA Coated
66	Stemsys Standard Cementless Stem Size 13	H73 0013	Standard Cementles Stem HA Coated
67	Stemsys Standard Cementless Stem Size 14	H73 0014	Standard Cementles Stem HA Coated
68	Stemsys Standard Cementless Stem Size 15	H73 0015	Standard Cementles Stem HA Coated
69	Stemsys Standard Cementless Stem Size 16	H73 0016	Standard Cementles Stem HA Coated
70	Stemsys Standard Cementless Stem Size 18	H73 0018	Standard Cementles Stem HA Coated
71	Stemsys Standard Cementless Stem Size 20	H73 0020	Standard Cementles Stem HA Coated



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
72	Stemsys Standard&Collared Cementless Stem Size 8	H73 C008	Standard&Collared Cementless Stem HA Coated
73	Stemsys Standard&Collared Cementless Stem Size 9	H73 C009	Standard&Collared Cementless Stem HA Coated
74	Stemsys Standard&Collared Cementless Stem Size 10	H73 C0010	Standard&Collared Cementless Stem HA Coated
75	Stemsys Standard&Collared Cementless Stem Size 11	H73 C0011	Standard&Collared Cementless Stem HA Coated
76	Stemsys Standard&Collared Cementless Stem Size 12	H73 C0012	Standard&Collared Cementless Stem HA Coated
77	Stemsys Standard&Collared Cementless Stem Size 13	H73 C0013	Standard&Collared Cementless Stem HA Coated
78	Stemsys Standard&Collared Cementless Stem Size 14	H73 C0014	Standard&Collared Cementless Stem HA Coated
79	Stemsys Standard&Collared Cementless Stem Size 15	H73 C0015	Standard&Collared Cementless Stem HA Coated
80	Stemsys Standard&Collared Cementless Stem Size 16	H73 C0016	Standard&Collared Cementless Stem HA Coated
81	Stemsys Standard&Collared Cementless Stem Size 18	H73 C0018	Standard&Collared Cementless Stem HA Coated
82	Stemsys Lateralised Cementless Stem Size 9	H73 L009	Lateralised Cementless Stem HA Coated
83	Stemsys Lateralised Cementless Stem Size 10	H73 L0010	Lateralised Cementless Stem HA Coated
84	Stemsys Lateralised Cementless Stem Size 11	H73 L0011	Lateralised Cementless Stem HA Coated
85	Stemsys Lateralised Cementless Stem Size 12	H73 L0012	Lateralised Cementless Stem HA Coated
86	Stemsys Lateralised Cementless Stem Size 13	H73 L0013	Lateralised Cementless Stem HA Coated
87	Stemsys Lateralised Cementless Stem Size 14	H73 L0014	Lateralised Cementless Stem HA Coated
88	Stemsys Lateralised Cementless Stem Size 15	H73 L0015	Lateralised Cementless Stem HA Coated
89	Stemsys Lateralised Cementless Stem Size 16	H73 L0016	Lateralised Cementless Stem HA Coated
90	Stemsys Lateralised Cementless Stem Size 18	H73 L0018	Lateralised Cementless Stem HA Coated
91	Stemsys Lateralised Cementless Stem Size 20	H73 L0020	Lateralised Cementless Stem HA Coated



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
92	Stemsys Lateralised&Collared Cementless Stem Size 9	H73 LC009	Lateralised&Collared Cementless Stem HA Coated
93	Stemsys Lateralised&Collared Cementless Stem Size 10	H73 LC0010	Lateralised&Collared Cementless Stem HA Coated
94	Stemsys Lateralised&Collared Cementless Stem Size 11	H73 LC0011	Lateralised&Collared Cementless Stem HA Coated
95	Stemsys Lateralised&Collared Cementless Stem Size 12	H73 LC0012	Lateralised&Collared Cementless Stem HA Coated
96	Stemsys Lateralised&Collared Cementless Stem Size 13	H73 LC0013	Lateralised&Collared Cementless Stem HA Coated
97	Stemsys Lateralised&Collared Cementless Stem Size 14	H73 LC0014	Lateralised&Collared Cementless Stem HA Coated
98	Stemsys Lateralised&Collared Cementless Stem Size 15	H73 LC0015	Lateralised&Collared Cementless Stem HA Coated
99	Stemsys Lateralised&Collared Cementless Stem Size 16	H73 LC0016	Lateralised&Collared Cementless Stem HA Coated
100	Stemsys Lateralised&Collared Cementless Stem Size 18	H73 LC0018	Lateralised&Collared Cementless Stem HA Coated
101	Stemsys Lateralised&Collared Cementless Stem Size 20	H73 LC0020	Lateralised&Collared Cementless Stem HA Coated
102	Stemsys Standard Cementless Revision Stem Size 8	H73 TC008	Standard Cementless Stem HA Coated
103	Stemsys Standard Cementless Revision Stem Size 9	H73 TC009	Standard Cementless Stem HA Coated
104	Stemsys Standard Cementless Revision Stem Size 10	H73 TC0010	Standard Cementless Stem HA Coated
105	Stemsys Standard Cementless Revision Stem Size 11	H73 TC0011	Standard Cementless Stem HA Coated
106	Stemsys Standard Cementless Revision Stem Size 12	H73 TC0012	Standard Cementless Stem HA Coated
107	Stemsys Standard Cementless Revision Stem Size 13	H73 TC0013	Standard Cementless Stem HA Coated
108	Stemsys Standard Cementless Revision Stem Size 14	H73 TC0014	Standard Cementless Stem HA Coated
109	Stemsys Standard Cementless Revision Stem Size 15	H73 TC0015	Standard Cementless Stem HA Coated
110	Stemsys Standard Cementless Revision Stem Size 16	H73 TC0016	Standard Cementless Stem HA Coated
111	Stemsys Standard Cementless Revision Stem Size 18	H73 TC0018	Standard Cementless Stem HA Coated



NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
112	Stemsys Standard Cementless Revision Stem Size 20	H73 TC0020	Standard Cementless Stem HA Coated
113	Co-Cr Femoral Head diameter 28mm & -7mm neck	H10 1279	Femoral Head in Cobalt-Chrome Alloy
114	Co-Cr Femoral Head diameter 28mm & -3.5mm neck	H10 1280	Femoral Head in Cobalt-Chrome Alloy
115	Co-Cr Femoral Head diameter 28mm & 0mm neck	H10 1281	Femoral Head in Cobalt-Chrome Alloy
116	Co-Cr Femoral Head diameter 28mm & +3.5mm neck	H10 1282	Femoral Head in Cobalt-Chrome Alloy
117	Co-Cr Femoral Head diameter 28mm & +7mm neck	H10 1283	Femoral Head in Cobalt-Chrome Alloy
118	Co-Cr Femoral Head diameter 28mm & +10.5mm neck	H10 1284	Femoral Head in Cobalt-Chrome Alloy
119	Co-Cr Femoral Head diameter 32mm & -4mm neck	H10 1320	Femoral Head in Cobalt-Chrome Alloy
120	Co-Cr Femoral Head diameter 32mm & 0mm neck	H10 1321	Femoral Head in Cobalt-Chrome Alloy
121	Co-Cr Femoral Head diameter 32mm & +4mm neck	H10 1322	Femoral Head in Cobalt-Chrome Alloy
122	Co-Cr Femoral Head diameter 32mm & +8mm neck	H10 1323	Femoral Head in Cobalt-Chrome Alloy
123	Co-Cr Femoral Head diameter 36mm & -4mm neck	H10 1360	Femoral Head in Cobalt-Chrome Alloy
124	Co-Cr Femoral Head diameter 36mm & 0mm neck	H10 1361	Femoral Head in Cobalt-Chrome Alloy
125	Co-Cr Femoral Head diameter 36mm & +4mm neck	H10 1362	Femoral Head in Cobalt-Chrome Alloy
126	Ceramic Femoral Head diameter 28mm & -3.5mm neck	H14 C1280	Femoral Head in Ceramic Composite
127	Ceramic Femoral Head diameter 28mm & 0mm neck	H14 C1281	Femoral Head in Ceramic Composite
128	Ceramic Femoral Head diameter 28mm & +3.5mm neck	H14 C1282	Femoral Head in Ceramic Composite
129	Ceramic Femoral Head diameter 32mm & -4mm neck	H14 C1220	Femoral Head in Ceramic Composite
130	Ceramic Femoral Head diameter 32mm & 0mm neck	H14 C1221	Femoral Head in Ceramic Composite





NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
131	Ceramic Femoral Head diameter 32mm & +4mm neck	H14 C1222	Femoral Head in Ceramic Composite
132	Ceramic Femoral Head diameter 36mm & -4mm neck	H14 1360	Femoral Head in Ceramic Composite
133	Ceramic Femoral Head diameter 36mm & 0mm neck	H14 1361	Femoral Head in Ceramic Composite
134	Ceramic Femoral Head diameter 36mm & +4mm neck	H14 1362	Femoral Head in Ceramic Composite
135	Ceramic Femoral Head diameter 40mm & -4mm neck	H14 1300	Femoral Head in Ceramic Composite
136	Ceramic Femoral Head diameter 40mm & 0mm neck	H14 1301	Femoral Head in Ceramic Composite
137	Ceramic Femoral Head diameter 40mm & +4mm neck	H14 1302	Femoral Head in Ceramic Composite
138	Stainless Steel Femoral Head diameter 22.2mm&-2mm neck	H11 1220	Femoral Head in Stainless Steel
139	Stainless Steel Femoral Head diameter 22.2mm&-0mm neck	H11 1221	Femoral Head in Stainless Steel
140	Stainless Steel Femoral Head diameter 22.2mm&+2mm neck	H11 1222	Femoral Head in Stainless Steel
141	Stainless Steel Femoral Head diameter 28mm&-7mm neck	H11 1279	Femoral Head in Stainless Steel
142	Stainless Steel Femoral Head diameter 28mm&-3.5mm neck	H11 1280	Femoral Head in Stainless Steel
143	Stainless Steel Femoral Head diameter 28mm& 0mm neck	H11 1281	Femoral Head in Stainless Steel
144	Stainless Steel Femoral Head diameter 28mm&+3.5mm neck	H11 1282	Femoral Head in Stainless Steel
145	Stainless Steel Femoral Head diameter 28mm&+7mm neck	H11 1283	Femoral Head in Stainless Steel
"End Of Product List"			

**SYARAT – SYARAT PENDAFTARAN PERANTI PERUBATAN**  
**MEDICAL DEVICE REGISTRATION CONDITIONS**

**1.0 SYARAT AM**  
**GENERAL CONDITIONS**

- 1.1 Syarat-syarat pendaftaran peranti perubatan ini dibuat adalah berdasarkan kepada Seksyen 7 (1), Akta Peranti Perubatan 2012 (Akta 737). Kelulusan ini diberi berdasarkan maklumat-maklumat yang telah diterima.  
*Medical device registration conditions are prescribed in accordance to Section 7(1) of Medical Device Act (Act 737). Approval is granted based on information received.*
- 1.2 Establismen hendaklah mematuhi segala arahan yang dikeluarkan oleh Pihak Berkuasa dari semasa ke semasa.  
*Establishment must comply with all instructions issued by the Authority from time to time.*
- 1.3 Pihak Berkuasa berhak untuk meminda syarat-syarat pendaftaran dari semasa ke semasa.  
*The Authority reserves the rights to amend the registration conditions from time to time.*
- 1.4 Pihak Berkuasa berhak untuk membuat lawatan atau pemeriksaan ke atas establismen pada bila-bila masa tanpa dimaklumkan terlebih dahulu.  
*The Authority reserves the right to conduct visit or inspection at any time without prior notice.*
- 1.5 Pihak Berkuasa boleh membatalkan Pendaftaran Peranti Perubatan atau mengambil tindakan undang-undang sekiranya Establismen gagal mematuhi mana-mana syarat Pendaftaran Peranti Perubatan.  
*The Authority may cancel the Medical Device Registration or take legal action if the Establishment fails to comply with any medical device registration conditions.*
- 1.6 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan oleh Pihak Berkuasa tidak boleh dipindah milik.  
*Medical Device Registration Certificate issued by the Authority shall not be transferable or assignable.*
- 1.7 Sijil Pendaftaran Peranti Perubatan hendaklah dikemukakan sekiranya diminta oleh mana-mana pegawai yang diberi kuasa.  
*Medical Device Registration Certificate must be presented upon request by any authorized officer.*
- 1.8 Establismen tidak boleh membenarkan Sijil Pendaftaran Peranti Perubatan disalahgunakan oleh individu/syarikat lain dalam apa-apa cara.  
*Establishment shall not permit the Medical Device Registration Certificate to be abused in any way by any individual / another party.*
- 1.9 Tempoh sahlaku Sijil Pendaftaran Peranti Perubatan adalah lima (5) tahun dari tarikh pendaftaran melainkan jika pendaftaran itu dibatalkan oleh Pihak Berkuasa sebelum habis tempohnya.  
*The validity of the Medical Device Registration Certificate is five (5) years from the date of registration unless the registration is cancelled by the Authority before its expiry.*
- 1.10 Pengiklanan peranti perubatan hendaklah tidak mengandungi apa-apa kenyataan yang boleh membawa maksud, sama ada secara langsung atau tidak langsung bahawa penggunaan peranti perubatan adalah dicadangkan, dipromosikan atau disahkan oleh Pihak Berkuasa atau mana-mana pihak yang berkaitan.  
*Advertising of medical device shall not contain any statement, whether directly or indirectly that the use of that medical device is suggested, promoted or endorsed by the Authority or another related party.*

- 1.11 Tujuan yang diniatkan bagi peranti perubatan hendaklah dinyatakan dengan jelas dalam iklan produk, termasuk brosur, risalah dan lain-lain, dan tidak boleh merujuk kepada mana-mana 20 jenis penyakit yang tidak boleh diiklankan seperti yang tertakluk kepada Seksyen 3(1) Akta Ubat (Iklan Dan Penjualan) 1956.  
*Intended purpose of medical device shall be clearly stated in the advertisement of products, including brochures, pamphlets, and etc., and shall not refer to any 20 types of diseases that cannot be advertised as prescribed in Section 3 (1) of the Medicines (Advertisement and Sale) Act 1956.*
- 1.12 Ia adalah menjadi tanggungjawab Establishmen untuk memastikan peranti perubatan mematuhi mana-mana keperluan undang-undang lain yang berkaitan. Sijil ini tidak mengecualikan mana-mana keperluan peraturan yang terpakai untuk peranti perubatan tersebut. (contoh: Peranti Perubatan yang mengandungi racun berjadual tertakluk kepada Akta Racun 1952; peranti perubatan menggunakan sinaran mengion adalah tertakluk kepada Akta Perlesenan Tenaga Atom 1984.)  
*It is the responsibility of the Establishment to ensure that medical device complies with any other requirements of the law. This certificate does not exclude any regulatory requirements applicable to medical device (for examples: Medical Device containing scheduled poison is subjected to the Poisons Act 1952; medical devices using ionizing radiation is subjected to the Atomic Energy Licensing Act 1984 ) .*
- 1.13 Establishmen hendaklah melaporkan insiden melibatkan peranti perubatan yang didaftarkan kepada Pihak Berkuasa seperti tertakluk di bawah Seksyen 40 Akta 737.  
*Establishment shall report any incidents involving registered medical device to the Authority as prescribed in Section 40 of Act 737.*
- 1.14 Peranti perubatan yang diniatkan bagi kegunaan professional hanya boleh dibekalkan untuk kegunaan professional perubatan sahaja dan tidak boleh diletakkan dipasaran bagi kegunaan orang awam.  
*Medical device intended for professional use may only be supplied for use by medical professionals only and shall not be placed in the market for general public.*

## **2.0 PINDAAN PENDAFTARAN PERANTI PERUBATAN AMENDMENT OF MEDICAL DEVICE REGISTRATION**

- 2.1 Sebarang pindaan kepada maklumat yang berkaitan peranti perubatan yang berdaftar hendaklah dimaklumkan kepada Pihak Berkuasa secara rasmi mengikut garis panduan yang ditetapkan oleh Pihak Berkuasa. Pihak Berkuasa berhak memberikan kelulusan atau menolak permohonan pindaan tersebut.  
*Any amendments to the information concerning registered medical device shall be notified to the Authority in accordance to the guidelines set by the Authority. The Authority reserves the right to grant approval or reject the application for such amendments.*

## **3.0 PEMBATALAN SIJIL PENDAFTARAN PERANTI PERUBATAN CANCELLATION OF MEDICAL DEVICE REGISTRATION CERTIFICATE**

- 3.1 Sijil Pendaftaran Peranti Perubatan boleh dibatalkan seperti yang dinyatakan dalam Seksyen 9, Akta 737.  
*Medical Device Registration may be cancelled as prescribed in Section 9 of Act 737.*
- 3.2 Mana-mana peranti perubatan yang dibatalkan Sijil Pendaftarannya, tidak boleh diimport, dieksport atau diletakkan dalam pasaran.  
*Any Medical Device which the registration certificate has been cancelled shall not be imported, exported or placed in the market.*

**4.0 HAK PIHAK BERKUASA  
THE AUTHORITY OWNERSHIP**

- 4.1 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan secara manual atau elektronik adalah Hak Milik Pihak Berkuasa.  
*The Authority retains the ownership of every Medical Device Registration Certificate issued by any means.*
- 4.2 Sekiranya berlaku kehilangan atau kerosakan Sijil Pendaftaran Peranti Perubatan, hendaklah dimaklumkan kepada Pihak Berkuasa dan setiap penggantian sijil akan dikenakan caj perkhidmatan.  
*Any loss or damage to the Medical Device Registration Certificate shall be notified to the Authority and every replacement of certificate shall be liable with service charge rendered.*

**5.0 TUGAS DAN TANGGUNGJAWAB  
ROLES AND RESPONSIBILITIES**

- 5.1 Establismen hendaklah mematuhi Akta 737, peraturan-peraturan di bawah Akta dan syarat-syarat Pendaftaran Peranti Perubatan.  
*Establishment shall comply with Act 737, its subsidiary regulations and registration conditions.*