



Certificate

The Malaysian Conformity Assessment Body

MEDCERT MALAYSIA SDN BHD - 18, 3rd floor, Jalan SS19/1D, 47500 Subang Jaya

herewith confirms that the company

**GLOBAL PRECISION SALES & SERVICES SDN BHD (987367-U)
A-03-05 Glomac Galeria,
Jalan 26A/70A,
Desa Sri Hartamas,
50480 Kuala Lumpur**

has introduced and applies a Regulatory Compliance System as an

**DISTRIBUTOR of medical devices
as per attachment 1- 12**

An audit demonstrated compliance of the Regulatory Compliance System with

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES

as per Medical Device Act 2012, Act 737 and Medical Device Regulations 2012

The certification assumes that the company is applying and maintaining its Regulatory Compliance System according to the above given requirements.

This certification is subject to surveillance by MEDCERT.

This certificate is valid until: 07 July 2018

Subang Jaya, 29 August 2015

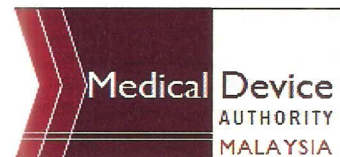
Process No.: QS - 9153

Certificate No.: 9153EN44020150829



MDA/CAB-002

General Manager
(Siew Yew Kong)





Attachment 1
Certificate QS-9153

No	NAME OF MEDICAL DEVICE	MANUFACTURER	BRAND/MODEL	Manufacturer Product Number/ Code	Grouping (single/family/system/test kit)	CLASS	GMDN CODE	Medical Device registration number
1	Portable Hearing Screening Device for OAE	Neurosoft Ltd.	Neuro_Audio Screen/OAE	UMDNS 17-601	System	B		—
2	Digital neurophysiological system for EP and OAE "Neuro-Audio" "	Neurosoft Ltd.	Neuro-Audio	UMDNS 11-474	System	B		—
3	AC40	Intercoustics	Intercoustics	8100099	Family	B		—
4	AD629	Intercoustics	Intercoustics	8016507	Family	B		—
5	AD226	Intercoustics	Intercoustics	8100664	Family	B		—
6	AS608	Intercoustics	Intercoustics	8000203	Family	B		—
7	PA5	Intercoustics	Intercoustics	8000174	Family	B		—
8	Callisto	Intercoustics	Intercoustics	8102741	Family	B		—
9	Equinox 2.0	Intercoustics	Intercoustics	8100115	Family	B		—
10	AT235	Intercoustics	Intercoustics	8016311	Family	B		—
11	AA222	Intercoustics	Intercoustics	8016380	Family	B		—
12	MT10	Intercoustics	Intercoustics	8101355	Family	B		—
13	Titan	Intercoustics	Intercoustics	8016073	Family	B		—
14	Eclipse	Intercoustics	Intercoustics	8100306	Family	B		—
15	Otoread	Intercoustics	Intercoustics	81052985	Family	B		—

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Subang Jaya, 29 August 2015


MDA/CAB-002
General Manager
(Siew Yew Kong)





Attachment 2 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
16	Affinity 2.0	Intercoustics	Intercoustics	8030892	Family	B		—
17	VIOT	Intercoustics	Intercoustics	8011495	Family	B		—
18	ZD-VOGfw	Intercoustics	Intercoustics	8011818	Family	B		—
19	VN415	Intercoustics	Intercoustics	8012415	Family	B		—
20	VO425	Intercoustics	Intercoustics	8012414	Family	B		—
21	VF405	Intercoustics	Intercoustics	8012421	Family	B		—
22	EyeSeeCam	Intercoustics	Intercoustics	8103917	Family	B		—
23	Air Fix	Intercoustics	Intercoustics	8013238	Family	B		—
24	Aqua Stim	Intercoustics	Intercoustics	8013247	Family	B		—
25	Rorary Chair (Nydiag 200)	Intercoustics	Intercoustics	8104353	Family	B		—
26	TBS25	Intercoustics	Intercoustics	8100778	Family	B		—
27	VRA201	Intercoustics	Intercoustics	8000177	Family	B		—
28	AC440	Intercoustics	Intercoustics	8012314	Family	B		—
29	REM440	Intercoustics	Intercoustics	8012318	Family	B		—
30	HIT440	Intercoustics	Intercoustics	8012316	Family	B		—
31	EP25	Intercoustics	Intercoustics	8018086	Family	B		—
32	EP15	Intercoustics	Intercoustics	8105193	Family	B		—
33	ABRIS	Intercoustics	Intercoustics	8018245	Family	B		—
34	ASSR	Intercoustics	Intercoustics	8018183	Family	B		—
35	TEOAE25	Intercoustics	Intercoustics	8018281	Family	B		—
36	DPOAE20	Intercoustics	Intercoustics	8018429	Family	B		—
37	VEMP	Intercoustics	Intercoustics	8017892	Family	B		—
38	ABRIS440	Intercoustics	Intercoustics	8012468	Family	B		—
39	TEOAE440	Intercoustics	Intercoustics	8100841	Family	B		—
40	DPOAE440	Intercoustics	Intercoustics	8012460	Family	B		—
41	IMP440	Intercoustics	Intercoustics	8104038	Family	B		—

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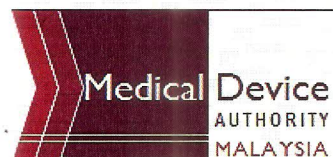
Attachment 3 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
42	Oticon Behind The Ear Hearing Aids	Oticon A/S	Oticon	114210	Family-BTE	B		—
43	Oticon Receiver-In-The –Ear Hearing Aids	Oticon A/S	Oticon	114088	Family-RITE	B		—
44	Oticon In-The –Ear Hearing Aids	Oticon A/S	Oticon	126162	Family-ITE	B		—
45	Oticon In-the – Canel Hearing Aids	Oticon A/S	Oticon	126158	Family-ITC	B		—
46	Oticon Completely-In-The-Canal Hearing Aids	Oticon A/S	Oticon	127920	Family-CIC	B		—
47	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 90 - 10	050-0079-P1	FAMILY-RIC	B	47169	—
48	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 90 - 312	050-0080-P1	FAMILY-RIC	B	47169	—
49	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 50 - 312T	050-0082-P1	FAMILY-RIC	B	47169	—
50	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 70 - 312T	050-0083-P1	FAMILY-RIC	B	47169	—
51	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 90 - 312T	050-0084-P1	FAMILY-RIC	B	47169	—
52	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q90 P	050-0114-P1	FAMILY-BTE	B	34671	—

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(Siew Yew Kang)




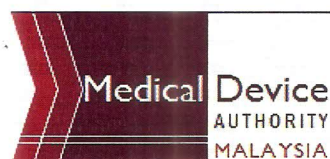


Attachment 4 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
53	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q90 SP	050-0115-P1	FAMILY-BTE	B	34671	—
54	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q90 M-13	050-0116-P1	FAMILY-BTE	B	34671	—
55	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q70 P	050-0118-P1	FAMILY-BTE	B	34671	—
56	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q70 SP	050-0119-P1	FAMILY-BTE	B	34671	—
57	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q50 M-13	050-0124-P1	FAMILY-BTE	B	34671	—
58	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q70 M-13	050-0129-P1	FAMILY-BTE	B	34671	—
59	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q50 P	050-0131-P1	FAMILY-BTE	B	34671	—
60	Hearing Aids	PHONAK AG	PHONAK/ Bolero Q50 SP	050-0132-P1	FAMILY-BTE	B	34671	—
61	Hearing Aids	PHONAK AG	PHONAK/ Naida Q 50 SP	050-0133-P1	FAMILY-BTE	B	34671	—
62	Hearing Aids	PHONAK AG	PHONAK/ Naida Q 70 SP	050-0134-P1	FAMILY-BTE	B	34671	—
63	Hearing Aids	PHONAK AG	PHONAK/ Naida Q 90 SP	050-0135-P1	FAMILY-BTE	B	34671	—

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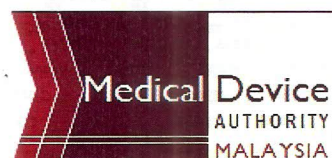
Attachment 5 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
64	Hearing Aids	PHONAK AG	PHONAK/Naida Q 50 UP	050-0136-P1	FAMILY-BTE	B	34671	—
65	Hearing Aids	PHONAK AG	PHONAK/Naida Q 70 UP	050-0137-P1	FAMILY-BTE	B	34671	—
66	Hearing Aids	PHONAK AG	PHONAK/Naida Q 90 UP	050-0138-P1	FAMILY-BTE	B	34671	—
67	Hearing Aids	PHONAK AG	PHONAK/Naida Q 50 RIC	050-0139-P1	FAMILY-RIC	B	47169	—
68	Hearing Aids	PHONAK AG	PHONAK/Naida Q 70 RIC	050-0140-P1	FAMILY-RIC	B	47169	—
69	Hearing Aids	PHONAK AG	PHONAK/Naida Q 90 RIC	050-0141-P1	FAMILY-RIC	B	47169	—
70	Hearing Aids	PHONAK AG	PHONAK/Audeo Q 70 - 10	050-0142-P1	FAMILY-RIC	B	47169	—
71	Hearing Aids	PHONAK AG	PHONAK/Audeo Q 50 - 10	050-0143-P1	FAMILY-RIC	B	47169	—
72	Hearing Aids	PHONAK AG	PHONAK/Audeo Q 70 - 312	050-0144-P1	FAMILY-RIC	B	47169	—
73	Hearing Aids	PHONAK AG	PHONAK/Audeo Q 50 - 312	050-0145-P1	FAMILY-RIC	B	47169	—
74	Hearing Aids	PHONAK AG	PHONAK/Naida Q 30 SP	050-0146-P1	FAMILY-BTE	B	34671	—

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Attachment 6 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
75	Hearing Aids	PHONAK AG	PHONAK/ Naida Q 30 UP	050-0147-P1	FAMILY-BTE	B	34671	—
76	Hearing Aids	PHONAK AG	PHONAK/ Naida Q 30 RIC	050-0148-P1	FAMILY-RIC	B	47169	—
77	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 30 - 10	050-0149-P1	FAMILY-RIC	B	47169	—
78	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 30 - 312	050-0150-P1	FAMILY-RIC	B	47169	—
79	Hearing Aids	PHONAK AG	PHONAK/ Audeo Q 30 - 312T	050-0151-P1	FAMILY-RIC	B	47169	—
80	Hearing Aids	PHONAK AG	PHONAK/ Sky Q50 M13	050-0163-P1	FAMILY-BTE	B	34671	—
81	Hearing Aids	PHONAK AG	PHONAK/ Sky Q 70 M13	050-0164-P1	FAMILY-BTE	B	34671	—
82	Hearing Aids	PHONAK AG	PHONAK/ Sky Q90 M13	050-0165-P1	FAMILY-BTE	B	34671	—
83	Hearing Aids	PHONAK AG	PHONAK/ Sky Q 50 SP	050-0166-P1	FAMILY-BTE	B	34671	—
82	Hearing Aids	PHONAK AG	PHONAK/ Sky Q 70 SP	050-0167-P1	FAMILY-BTE	B	34671	—
83	Hearing Aids	PHONAK AG	PHONAK/ Sky Q 90 SP	050-0168-P1	FAMILY-BTE	B	34671	—
84	Hearing Aids	PHONAK AG	PHONAK/ Sky Q 50 UP	050-0176-P1	FAMILY-BTE	B	34671	—

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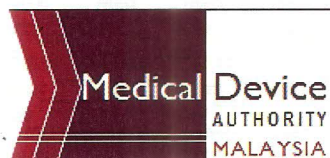


Attachment 7
Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
85	Hearing Aids	PHONAK AG	PHONAK / Sky Q 70 UP	050-0177-P1	FAMILY-BTE	B	34671	—
86	Hearing Aids	PHONAK AG	PHONAK / Sky Q 90 UP	050-0178-P1	FAMILY-BTE	B	34671	—
87	Hearing Aids	PHONAK AG	PHONAK / Baseo Q 15 M	050-0182-01	FAMILY-BTE	B	34671	—
88	Hearing Aids	PHONAK AG	PHONAK /Baseo Q 15 - P	050-0183-01	FAMILY-BTE	B	34671	—
89	Hearing Aids	PHONAK AG	PHONAK /Baseo Q 15 - SP	050-0184-01	FAMILY-BTE	B	34671	—
90	Hearing Aids	PHONAK AG	PHONAK / Bolero Q 30 - P	050-0191-P1	FAMILY-BTE	B	34671	—
91	Hearing Aids	PHONAK AG	PHONAK / Bolero Q 30 - SP	050-0192-P1	FAMILY-BTE	B	34671	—
92	Hearing Aids	PHONAK AG	PHONAK / Bolero Q 30 M-13	050-0193-P1	FAMILY-BTE	B	34671	—
93	Hearing Aids	PHONAK AG	PHONAK / Sky Q 50 RIC	050-0205-P1	FAMILY-RIC	B	47169	
94	Hearing Aids	PHONAK AG	PHONAK / Sky Q 70 RIC	050-0206-P1	FAMILY-RIC	B	47169	

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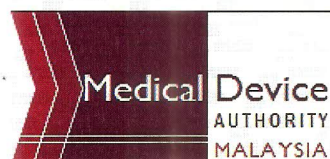


Attachment 8 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
95	Hearing Aids	PHONAK AG	PHONAK / Sky Q 90 RIC	050-0207-P1	FAMILY-RIC	B	47169	—
96	Hearing Aids	PHONAK AG	PHONAK / Cassia microP	050-0448-01	FAMILY-BTE	B	34671	—
97	Hearing Aids	PHONAK AG	PHONAK / Cassia SP	050-0449-01	FAMILY-BTE	B	34671	—
98	Hearing Aids	PHONAK AG	PHONAK / Audeo S Smart III	050-0941-F6	FAMILY-RIC	B	47169	—
99	Hearing Aids	PHONAK AG	PHONAK / Naida S III SP	050-0956-01	FAMILY-BTE	B	34671	—
100	Hearing Aids	PHONAK AG	PHONAK / Naida S III UP	050-0959-01	FAMILY-BTE	B	34671	—
101	Hearing Aids	PHONAK AG	PHONAK / Audeo S Smart I	050-0965-F6	FAMILY-RIC	B	47169	—
102	Hearing Aids	PHONAK AG	PHONAK / Cassia M H2O	050-0973-01	FAMILY-BTE	B	34671	—
103	Hearing Aids	PHONAK AG	PHONAK / CROS H2O	050-0986-P1	FAMILY-BTE	B	34671	—
104	Hearing Aids	PHONAK AG	PHONAK / Dalia M H2O	050-0987-01	FAMILY-BTE	B	34671	—
105	Hearing Aids	PHONAK AG	PHONAK / Dalia Micro P	050-0989-01	FAMILY-BTE	B	34671	—

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Attachment 9 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
106	Hearing Aids	PHONAK AG	PHONAK / Dalia SP	050-0990-01	FAMILY-BTE	B	34671	—
107	Hearing Aids	PHONAK AG	PHONAK / Naida S I SP	050-0991-01	FAMILY-BTE	B	34671	—
108	Hearing Aids	PHONAK AG	PHONAK / Naida S I UP	050-0992-01	FAMILY-BTE	B	34671	—
109	Hearing Aids	PHONAK AG	PHONAK / Virto Q 30-10 / SP	063-0009-01	FAMILY-ITE	B	41209	—
110	Hearing Aids	PHONAK AG	PHONAK / Virto Q30-312 / SP	063-0013-01	FAMILY-ITE	B	41209	—
111	Hearing Aids	PHONAK AG	PHONAK / Virto Q30-13 / SP	063-0015-01	FAMILY-ITE	B	34672	—
112	Hearing Aids	PHONAK AG	PHONAK / Tao 15-10 / SP	063-0017-01	FAMILY-ITE	B	41209	—
113	Hearing Aids	PHONAK AG	PHONAK / Tao Q15 312 / SP	063-0019-01	FAMILY-ITE	B	41209	—
114	Hearing Aids	PHONAK AG	PHONAK / Tao Q15-13 / SP	063-0021-01	FAMILY-ITE	B	34672	—

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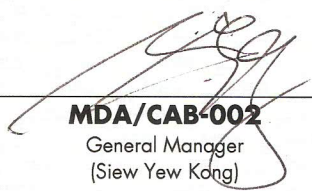


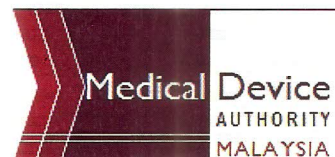


Attachment 10 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
115	Hearing Aids	PHONAK AG	PHONAK / Virto Q90 Nano CIC	063-0071-01	FAMILY-ITE	B	41209	—
116	Hearing Aids	PHONAK AG	PHONAK / Virto Q90 10 / SP	063-0072-01	FAMILY-ITE	B	41209	—
117	Hearing Aids	PHONAK AG	PHONAK / Virto Q90 312 / SP	063-0074-01	FAMILY-ITE	B	41209	—
118	Hearing Aids	PHONAK AG	PHONAK / Virto Q90 13 / SP	063-0076-01	FAMILY-ITE	B	34672	—
119	Hearing Aids	PHONAK AG	PHONAK / Virto Q70 Nano CIC	063-0077-01	FAMILY-ITE	B	41209	—
120	Hearing Aids	PHONAK AG	PHONAK / Virto Q70 10 / SP	063-0078-01	FAMILY-ITE	B	41209	—
121	Hearing Aids	PHONAK AG	PHONAK / Virto Q70 312 / SP	063-0081-01	FAMILY-ITE	B	41209	—

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Attachment 11 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
122	Hearing Aids	PHONAK AG	PHONAK / Virto Q70 13 / SP	063-0082-01	FAMILY-ITE	B	34672	—
123	Hearing Aids	PHONAK AG	PHONAK / Virto Q50 Nano CIC	063-0083-01	FAMILY-ITE	B	41209	—
124	Hearing Aids	PHONAK AG	PHONAK /Virto Q50-10 / SP	063-0084-01	FAMILY-ITE	B	41209	—
125	Hearing Aids	PHONAK AG	PHONAK /Virto Q50-312 / SP	063-0087-01	FAMILY-ITE	B	41209	—
126	Hearing Aids	PHONAK AG	PHONAK / Virto Q50- 13 / SP	063-0088-01	FAMILY-ITE	B	34672	—
127	Hearing Aids	PHONAK AG	PHONAK / CROS FS 13	063-0122-01	FAMILY-ITE	B	34672	—
128	Hearing Aids	PHONAK AG	PHONAK / Dalia 10 Petite / SP	063-0123-01	FAMILY-ITE	B	41209	—
129	Hearing Aids	PHONAK AG	PHONAK / Dalia 312 / SP	063-0124-01	FAMILY-ITE	B	41209	—

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Attachment 12 Certificate QS-9153

No.	Name of Medical Device	Manufacturer	Brand / Model	Manufacturer Product No.	Grouping - Single - Family - System - Test kit	Class	GMDN Code	Medical Device Registration No.
130	Hearing Aids	PHONAK AG	PHONAK / Dalia 13 / SP	063-0125-01	FAMILY-ITE	B	34672	—
131	Hearing Aids	PHONAK AG	PHONAK / Cassia 10 Petite / SP	063-0437-01	FAMILY-ITE	B	41209	—
132	Hearing Aids	PHONAK AG	PHONAK / Cassia 312 UZ / SP	063-0449-01	FAMILY-ITE	B	41209	—
133	Hearing Aids	PHONAK AG	PHONAK / Cassia 13 UZ / SP	063-0452-01	FAMILY-ITE	B	34672	—
134	Hearing Aids	PHONAK AG	PHONAK / Cassia Nano CIC	063-0481-01	FAMILY-ITE	B	41209	—

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