



DEVICE DETAILS

NAME OF DEVICE	QTUBE BREATHING CIRCUIT
ESTABLISHMENT NAME	AARGYP SCIENTIFIC SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10703819-29150
BRAND NAME	ENVISEN
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Breathing Circuits which are disposable and generally recommended for Single Use when supplied as is. A breathing circuit transfers gas and air mixtures from the anaesthetic machine/ventilator to the patient to ensure they remain under anaesthetic and suitably perfused with oxygen and from the patient to the anaesthetic machine/ventilator to ensure entidal carbon dioxide levels are drawn off from the patient at the same time. Standard corrugated circuits have a high turbulent effect on gas flow through the tube, which in turn creates high flow resistance. This is why a standard circle breathing circuit has two large tubes, inspiratory and expiratory to keep resistance to an acceptable level. The Qtube™ incorporates a smooth, bilumen inner wall design, which significantly improves internal flow and breathing resistance. The Qtube has been designed as single, small, low volume tube.
DEVICE INTENDED PURPOSE	A breathing circuit transfers gas and air mixtures from the anesthetic machine/ventilator to the patient to ensure they remain under anesthetic and suitably perfuse with oxygen and from the patient to the anesthetic machine/ventilator to ensure entidal carbon dioxide levels are drawn off from the patient at the same time.
VALIDITY DATE OF REGISTRATION	04/06/2024 - 03/06/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Qtube™ Paediatric to Adult 1.5m Long Disposable Circuit Only	Q112215P
2	Qtube™ Paediatric to Adult 1.8m Long Disposable Circuit Only	Q112218P
3	Qtube™ Paediatric to Adult 2.4m Long Disposable Circuit Only	Q112224P
4	Qtube™ Paediatric to Adult 3.0m Long Disposable Circuit Only	Q112230P
5	Qtube™ Paediatric to Adult 1.5m Long Disposable Circuit-Complete	Q112215P-18BC2L
6	Qtube™ Paediatric to Adult 1.8m Long Disposable Circuit-Complete	Q112218P-18BC2L

NO	NAME OF DEVICE	IDENTIFIER
7	Qtube™ Paediatric to Adult 2.4m Long Disposable Circuit-Complete	Q112224P-18BC2L
8	Qtube™ Paediatric to Adult 3.0m Long Disposable Circuit-Complete	Q112230P-18BC2L
9	Qtube™ Paediatric to Adult 1.5m Long Disposable Circuit-With Integrated Gas Sampling Line	Q112215P-IGS
10	Qtube™ Paediatric to Adult 1.8m Long Disposable Circuit-With Integrated Gas Sampling Line	Q112218P-IGS
11	Qtube™ Paediatric to Adult 2.4m Long Disposable Circuit-With Integrated Gas Sampling Line	Q112224P-IGS
12	Qtube™ Paediatric to Adult 3.0m Long Disposable Circuit-With Integrated Gas Sampling Line	Q112230P-IGS
13	Qtube™ Paediatric to Adult 1.5m Long Disposable Circuit-With Integrated Gas Sampling Line & Rebreathing Bag	Q112215N-IGS18BC2L
14	Qtube™ Paediatric to Adult 1.8m Long Disposable Circuit-With Integrated Gas Sampling Line & Rebreathing Bag	Q112218P-IGS18BC2L
15	Qtube™ Paediatric to Adult 2.4m Long Disposable Circuit-With Integrated Gas Sampling Line & Rebreathing Bag	Q112224P-IGS18BC2L
16	Qtube™ Paediatric to Adult 3.0m Long Disposable Circuit-With Integrated Gas Sampling Line & Rebreathing Bag	Q112230P-IGS18BC2L
17	Qtube™ Paediatric to Adult, 1.8m non-expandable, fixed wye & gas sampling port	C152218P
18	Qtube™ Paediatric to Adult, 1.8m non-expandable, fixed wye & gas sampling port, 1.8m extension limb (blue) with 2L breathing bag	C152218P-18B2CL
19	Qtube™ Paediatric to 3.0m Gas Sampling Line Male/Male	QP8003
20	Qtube™ Paediatric to 3.0m Gas Sampling Line Male/Female	QP8103
21	Qtube™ Paediatric to Ped, 1.5m non-expandable, fixed wye & gas sampling port	C151515P
22	Qtube™ Paediatric to Ped, 1.5m non-expandable, fixed wye & gas sampling port, 1.5m extension limb (blue) with 1L breathing bag	C151515P-15BC1L
23	Qtube™ Paediatric to Adult, 3.0m expandable, fixed wye with gas sampling port	E152230P
24	Qtube™ Paediatric to Ped, 3.0m expandable, fixed wye with gas sampling port	E151530P

NO	NAME OF DEVICE	IDENTIFIER
25	Qtube™ Paediatric to Adult, 2.4m non-expandable, fixed wye with gas sampling port	C152224P



MEDICAL DEVICE AUTHORITY