

## Certificate of registration / Registreringsbevis

Manufacturer or Authorised Representative / Tillverkare eller Auktoriserad Representant

Organisation:	Fogless International AB
Organisation no/Organisationsnr:	556372-7717
Postal address/Postadress:	Box 84, 551 12 Jönköping

**This certificate is valid until / Detta registreringsbevis gäller till: 2012-09-30**

Medical Products Agency hereby confirms that the above mentioned manufacturer/authorised representative has registered the listed medical devices in accordance with the regulations issued by Medical Products Agency

- LVFS 2003:11 on medical devices
- LVFS 2001:7 on medical devices for in vitro diagnostics
- LVFS 2001:5 on active implantable medical devices

The manufacturer or his authorised representative is responsible for the products listed in this certificate and must ensure that they are in accordance with the legislation in force (the Act (1993:584) on medical devices and the regulations issued by Medical Products Agency, LVFS 2003:11, LVFS 2001:7, LVFS 2001:5)

Läkemedelsverket bekräftar härmed att ovan angivna tillverkare/auktoriserade representant fullgjort sin skyldighet att registrera angivna medicintekniska produkter i enlighet med kraven i Läkemedelsverkets föreskrifter

- LVFS 2003:11, om medicintekniska produkter
- LVFS 2001:7, om medicintekniska produkter för in vitro diagnostik
- LVFS 2001:5 om aktiva medicintekniska produkter för implantation

Tillverkaren eller dennes auktoriserade representant, svarar för att de produkter som ingår i detta bevis uppfyller kraven i gällande författningar (lag (1993:584) om medicintekniska produkter samt Läkemedelsverkets föreskrifter LVFS 2003:11, LVFS 2001:7; LVFS 2001:5).

### Products / Produkter

PID	Product/Produkt	Article No/Artikelnr	Product class /Produktklass	GMDN
12273	SPIRO Speaking Valve without oxygen nipple	711	MD, Klass I	36071
12274	SPIRO Shower protection device (710/711)	730	MD, Klass I	36071
25597	SPIRO Adaptor for silver cannula Ø13mm	707	MD, Klass I	35074
25598	SPIRO Adaptor for silver cannula Ø14mm	708	MD, Klass I	35074
32671	SPIRO Shower protection device (702)	703	MD, Klass I	41189