

## Certificate of registration / Registreringsbevis

Manufacturer or Authorised Representative / Tillverkare eller Auktoriserad Representant

|                                  |                         |
|----------------------------------|-------------------------|
| Organisation:                    | Kibion AB               |
| Organisation no/Organisationsnr: | 556610-9814             |
| Postal address/Postadress:       | Box 303, 751 05 Uppsala |

**This certificate is valid until / Detta registreringsbevis gäller till: 2014-06-13**

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

| <u>PID</u> | <u>Product/Produkt</u> | <u>Article No/Artikelnr</u> |                | <u>GMDN</u> |
|------------|------------------------|-----------------------------|----------------|-------------|
| 64104      | Heliprobe Analyzer     | HPU-011                     | IVD, Generella | 44204       |
| 64105      | Heliprobe BreathCard   | HPC-001                     | IVD, Generella | 44204       |