Certificate of registration / Registreringsbevis

Manufacturer or Authorised Representative / Tillverkare eller Auktoriserad Representant

Organisation:	Qbtech AB
Organisation no/Organisationsnr:	556624-6996
Postal address/Postadress:	Kungsgatan 29, 111 56 Stockholm Sweden

This certificate is valid until / Detta registreringsbevis gäller till: 2020-05-25

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 fö reskrifter
- 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 Lä kemedelsverkets föreskrifter LVFS 2003:11, LVFS 2001:7; LVFS 2001:5).

Products / Produkter

PID	Product/Produkt	Article No/Artikelnr	Riskclass	GMDN
35368	QbTest	0100	MD, Klass I	30895
57366	QbTest-Motus		MD, Klass I	30895
60104	Qb Test-Plus		MD, Klass I	30895
144340	QbCheck	0200	MD, Klass I	30895

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0) 18 17 46 00 Fax: +46 (0) 18 50 31 15
Internet: www.lakemedelsverket.se E-mail: meddev.central@lakemedelsverket.se

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY
Medical Devices
Lilian Nilsson

Public statement

Date: 2020-05-28

To whom ít may concern

Validity of certificates of registration for medical devices

Any certificates of registration from the Swedish Medical Products Agency with a validity that expired on 2020-05-25 is considered valid until the holder of such a certificate has completed a renewed registration and received a confirmation of registration or 2020-09-30 at the latest.

The prolongation of validity is due to the handling of the delay of both the application of regulation 2017/745 (MDR) and a fully functional Eudamed. The Swedish Medical Products Agency will continue to handle registration of medical devices placed on the market by manufacturers established in Sweden or with the support of authorized representatives established in Sweden until Eudamed is fully functional.

In this document, the denomination “medical devices” include:

- CE-marked medical devices
- CE-marked active implantable medical devices
- CE-marked medical devices for in vitro diagnostics
- custom-made medical devices
- systems and procedure packs

Please note that the confirmation of registration that will be issue from now on will not have a date when the validity expires. It will be dated when the registration is completed.

On behalf of the Swedish Medical Products Agency,

Lilian Nilsson
Manager Regulatory and Guidance for Medical Devices

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