

# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

**Organization:**

## Black Tie Medical, Inc

Main Site: 4360 Morena Blvd., Suite 100, San Diego, California, 92117,  
United States

**Product Category:**

- Non-active devices and accessories for injection, infusion and  
transfusion

For further identification of the products covered, see the MDD product list/product schedule.

**Certificate Number:**

4130113841

**Initial Certification Date:**

17 May 2021

**Certificate Valid from:**

17 May 2021

**Certificate Expiry Date:**

26 May 2024



**Mikael Hagelin**

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

17 May 2021

**Signed Date**

Intertek Semko AB  
Box 1103, SE-164 22 Kista, Sweden  
Telephone +46 8 750 00 00  
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

