

EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production 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 V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Becton, Dickinson and Company Limited

Main Site: Pottery Road, Dun Laoghaire, Co. Dublin, Ireland

Product Category:

- Closed system drug-transfer device

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

Certificate Number:

41319062-03

Initial Certification Date:

24 July 2012

Certificate Valid from:

9 June 2020

Certificate Expiry Date:

26 May 2024



Accred. no. 1003
Certification of
Management
Systems
ISO/IEC 17021-1

Bob Andersson

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

9 June 2020

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.

