

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:

Axiom Medical, Inc.

Main Site: 19320 Van Ness Avenue, Torrance, California, 90501, United States

Product Category:

- Thoracic Catheter and Mediastinal Drains

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

Certificate Number:

413107988-00

Initial Certification Date:

2 December 2020

Certificate Valid from:

2 December 2020

Certificate Expiry Date:

26 May 2024



Bob Andersson

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2 December 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.

