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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.

Certificate Number:
41371231-03

Initial Certification Date:
22 January 2018*

Certificate Valid from:
22 January 2019

Certificate Expiry Date:
21 January 2024

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Organization:

Shenzhen Homed Medical Device Co., Ltd.

Main Site: 3rd Floor, Block 1, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China

Product Category:

- Nebulizers, Suction devices and Oxygen concentrators

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

*Previously certified by Intertek AMTAC (NB0473) to date 21 January 2018

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

18 January 2019
Signed Date

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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.