

PREPARING ETO STERILIZATION REPORT

GLOBAL MEDICAL DEVICE CONSULTING

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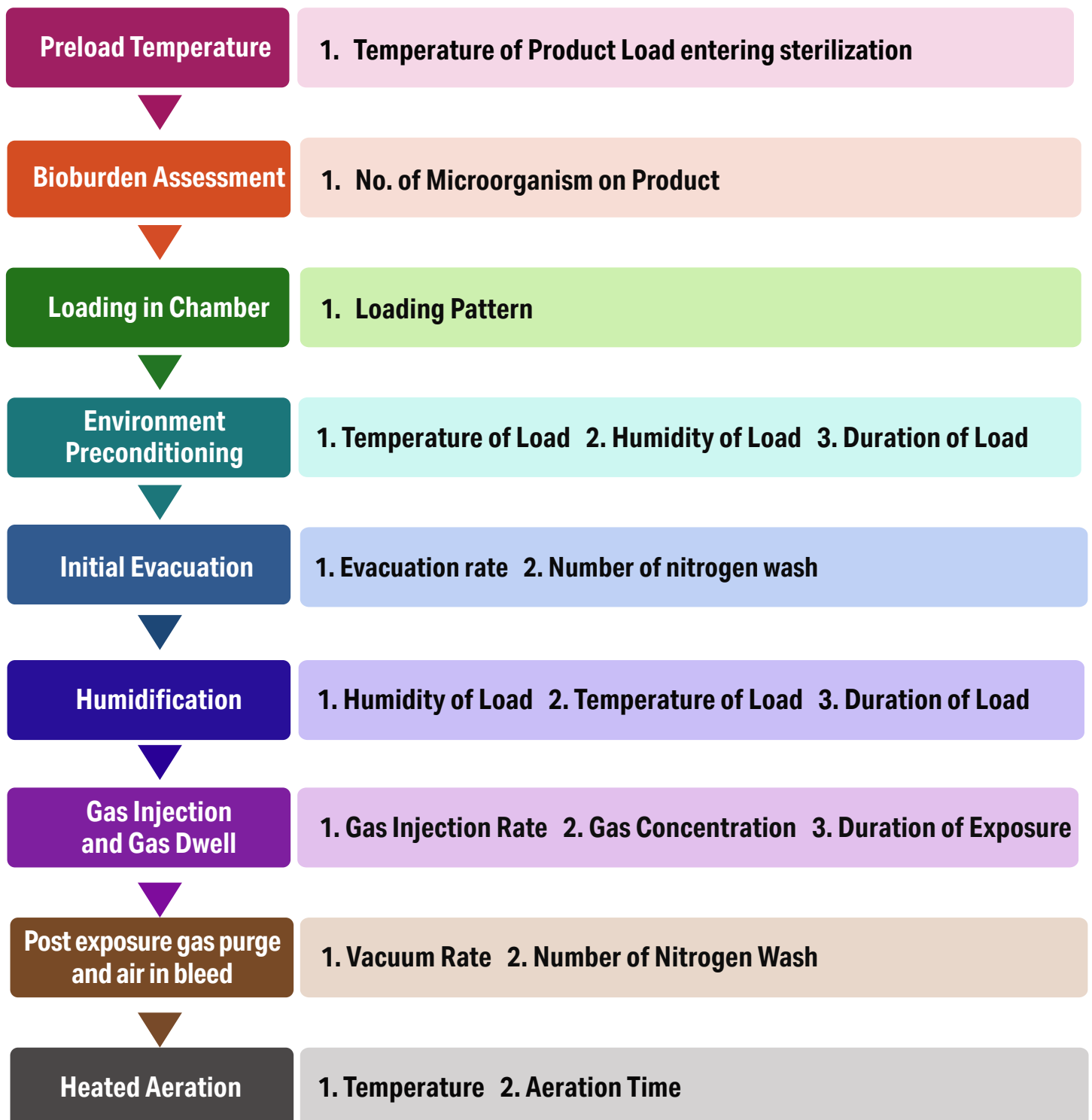
Vee VEE CARE (ASIA) LTD



MD 653109

PREPARING ETO STERILIZATION REPORT

ETO STERILIZATION PROCESS



PREPARING ETO STERILIZATION REPORT

DOCUMENTS REQUIRED

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1. Validation Protocol

2. Biological Indication Certificate of Performance

3. Biological Indicator Enumeration Test Reports

4. Bioburden Test Reports

5. Bacteriostasis / Fungistasis Test Reports

6. Physical/Biological Data – Fractional Cycle

7. Physical/Biological Data – Half Cycle One

8. Physical/Biological Data– Half Cycle Two

9. Physical/Biological Data– Half Cycle Three

10. Physical/Biological Data – Full Cycle One

11. Physical/Biological Data – Full Cycle Two (optional)

12. Physical/Biological Data – Full Cycle Three (optional)

13. ETO Residue Report

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www.vee-med.com



HONG KONG*

17/F, Chung Pont Commercial Building
300 Hennessy Road, Wanchai
Hong Kong

USA

4610 Highland Drive
Salt Lake City, UT 84117
USA

TAIWAN*

Unit 25, 9th Floor
No. 188, Section, 4 ChengGong Road
Neihu District, 114 Taipei City
Taiwan

AUSTRALIA

Level 25, 100 Mount Street North
Sydney, NSW 2060
Australia

CHINA

Room 100, 212, 2nd Floor
9-11 Jiangong Road, Zhongshan Avenue
TianHe District, Guangzhou
China

UK

Unit 808, 54 Bloomfield Avenue
Belfast, BT5 5AD, Northern Ireland
United Kingdom