

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2158141-1

Certificate Holder: Shenzhen Boon Medical Supply Co., Ltd.
No.18 Jirong Road, Shenkeng,
Henggang Street, Longgang District,
518173 Shenzhen, P.R. China

Scope: Design and Development, Manufacture and Distribution of

- Sterile High-pressure Angiographic Syringes for Single-use
- Sterile High-pressure Angiographic Syringes for Multi-use
- Pressure Connecting Tubes for Single use
- Cervical ripening balloon for single use
- Hemostasis valve set for single use
- Dose-control syringe for single use
- Manifold for single use

Manufacture and Distribution of

- Sterile Syringes with Needle for Single-use
- Sterile Infusion Sets with Needle for Single-use
- Sterile Infusion Connecting Tubes for Single-use
- Sterile Venous Blood Sampling Needles for Single-use
- Sterile Scalp Needles for Single-use
- Sterile Vaginal Dilators for Single-use
- Sterile Balloon Expansion Pressure Syringes for Single-use
- Single-use Containers for Human Venous Blood Specimen Collection
- Single Use Laryngoscope Blades

Provision of Ethylene Oxygen Sterilization Service in accordance with EN ISO 11135:2014

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10922651-100

Effective date: 2023-11-21

Expiry date: 2026-11-08

Issue date: 2023-11-21

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This certificate can be validated on <https://www.certipedia.com>



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