TERUMO MEDICAL CORPORATION

950 Elkton Boulevard Elkton, MD 21921 Telephone (410) 398-8500, Fax (410) 392-7218

CERTIFICATE OF COMPLIANCE CERTIFICATE OF STERILITY

Date: 01/30/2015

Lot Number: 140616C

Product Code: SG3-1825

Expiration Date: 2019 - 05

Product Description: SURGUARD3 18GX1 SAFETY NEEDLE

- 1. All Terumo products are manufactured in accordance with established product specifications and in accordance with the US Food, Drug, and Cosmetic Act, Chapter 21, Part 820, pertaining to: Quality System Regulations (Current Good Manufacturing Practices for Medical Devices) GMPs.
- 2. All incoming raw material meets specified requirements for material type, grade, and physical/chemical properties. Quality testing and review is performed on all raw materials in order to provide production areas with the caliber of materials necessary to manufacture finished product devices that meet specifications.
- 3. The visual and physical controls are checked in accordance with Terumo Specifications based on EN/ISO standards. Quality testing and document review is performed prior to release of finished devices to assure product performance to specifications.

- visual inspection : conform

- physical performance : conform

4. This lot is certified to be sterile and non-pyrogenic.

Kathleen Little, PhD Quality Systems Manager Terumo Medical Corporation