


Certificate of Quality and Compliance

This is to certify that the below listed kits have been assembled in accordance with provided specifications in an appropriately licensed and/or registered facility operating under a Global Quality Management System compliant to the United States Food and Drug Administration's current Good Manufacturing Practices for medical devices, 21 CFR § 820, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the (Singapore) Health Sciences Authority's Good Distribution Practice for Medical Devices – Requirements.

Upon completion, a representative sample was inspected for Quality using the ANSI General Inspection Level III, Single Sampling standard and inspection criteria relevant to product specifications and shelf-life expectations. Inspection reports are retained for a period of 60 months unless otherwise required.

| <u>Product Description</u> | <u>Lot Number</u> | <u>Exp. Date</u> |
|----------------------------|-------------------|------------------|
| Generic NanoCool – Large | 56850G19002 | 31-Aug-2020 |

By: 
(Signature)
Jorge Huerta
(Print Name)
Quality Manager
(Title)
11-Feb-19
(Date)

Claremont, CA State of California Department of Health Services, Food and Drug Branch, Device Manufacturer License # 74204
Claremont, CA California State Board of Pharmacy Wholesaler license # WLS 6993
All US facilities Food and Drug Administration Department of Health and Human Services, Public Health Service, Owner/Operator # 9002081
Claremont, CA Food and Drug Administration Department of Health and Human Services, Public Health Service, Registered Establishment # 3010882984
Buford, GA Food and Drug Administration Department of Health and Human Services, Public Health Service, Registered Establishment # 3006450277
London, UK Department of Health, Medicines and Healthcare products Regulatory Agency ref CA 009316