RICHLINE GROUP
A Berkshire Hathaway Company

inverness
Safe & Gentle Ear Piercing

CERTIFICATE OF CONFORMANCE

Sterilization/Guarantee of Microbial Integrity of Inverness Products

Richline Group, d/b/a Inverness is dedicated to providing safe and sterile products to all of our customers, and the company utilizes every means available to do so. Inverness produces both a Class 1 Medical Device as well as a topically applied pharmaceutical treatment for post piercing aftercare. All products are registered with the FDA and comply with all applicable requirements.

MEDICAL DEVICE/EAR PIERCING

Productions of our piercing earrings and their guarantee of sterility are ensured by our double-redundant and fully-traceable method of sterilization. “Steri-dots” are applied to every master box of earrings produced by Richline Group, d/b/a Inverness. When exposed to ethylene oxide gas, our sterilization method, the dots turn from red to green. This change in color indicates that the product has been exposed to the sterilizing effect of the gas for the proper period of time to guarantee a full kill of all contaminants. Ethylene oxide is the sterilizing component used by hospitals to sterilize surgical tools.

Biological indicators are placed strategically throughout pallets of product being sterilized as a second indicator of a complete biological kill. The placements of the indicators are determined by a comparative study of the loading of the materials to be sterilized. The biological indicators are then sent out to an independent, accredited testing laboratory for analysis.

Inverness 2000 Cassettes are sterilized with Ethylene Oxide using a process validated with ISO 11135 and EN550. The validation of each sterilization is carried out according to ISO 11737-2 current revision.

Additionally the FDA accredited sterilization facility provides a report on every lot of product that they sterilize for Inverness. Included in the report are the following documents:

- A Certificate of Sterilization Process
- A Load Release Checklist
- A Sterilization Record
- A Sterilizer Cycle Chart recording for Temperature and Vacuum
- A Preconditioner and Aeration Room Chart Recording

- A Biological Indicator Placement Diagram
- Interplant Transfer Sheets
- A Sterility Test Report

All documents are signed and dated by an authorized representative of the sterilization company.

TOPICALLY-APPLIED EAR CARE ANTISEPTIC.

Inverness Ear Care Antiseptic is manufactured on site and under the complete control of Inverness Corporation. Inverness utilizes the same care and handling of its Ear Care Antiseptic (ECA) as it does its Class 1 Medical Device to guarantee the safety and sterility of all of our products. ECA is as important to a proper ear piercing and healing process as is the sterile earring.

Inverness uses a reverse osmosis process to eliminate all contaminants in the water used in the production of ECA. The water used in the manufacture of this product is devoid of all potential contaminants including bacterial and microbial matter.

ECA is manufactured through a batch process and is fully lot-traceable. All lots of products are tested by an independent, accredited testing laboratory. Product is held in quarantine until the proper release information is received from the accredited testing laboratory.

COPIES OF ALL TESTING RESULTS ARE ON FILE AT RICHLINE GROUP, D/B/A INVERNESS CORPORATION IN ATTLEBORO, MASSACHUETTS.

Sincerely,

Serfilex Reyes
Quality assurance engineer