RICHLINE GROUP
A Berkshire Hathaway Company

inverness
Safe & Gentle Ear Piercing

DECLARATION OF CONFORMITY

To whom it may concern,

This is to certify that all Ear Piecing Earring Inverness brand conform to:

European Union Directive 2004/96EC Amendment to the Restrictions on the Marketing and Use of Nickel for Piercing Post Assemblies, limiting nickel release to no more than 0.2µgm/cm2/week.

Using nickel release reference test method: [EN 12472:2005+A1:2009 & EN 1811:2011+A1:2015, REACH Annex XVII entry 27].

In addition all Ear Piecing Earring Inverness brand conform to European Union Directive 2004/96EC:

- REACH Annex XVII entry 51-52-Phtalate
- REACH Annex XVII entry 63 Lead and its compounds
- REACH Annex XVII entry 23 Cadmium and its compounds
- REACH Annex XVII entry 66 Bisphenol A.

MEDICAL DEVICE/EAR PIERCING

According to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, ANNEX XVI, LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2) Paragraph 2. Inverness Ear Piercing System is not classified as medical into the EU countries.

However according to US medical device regulation, Inverness DBA Richline Group had described its products as Inverness Ear piercing System Perforator Ear-Lobe and nose– Inverness Piercing.

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 Ear piercing Systems is registered with the FDA and comply with all applicable requirements.

Based on the 21 CFR 874-- EAR, NOSE, AND THROAT DEVICES, Subpart E--Surgical Devices, Sec. 874.4420 Ear, nose, and throat manual surgical instrument, Paragraph (A) the FDA had classified the Inverness Ear piercing System, Perforator Ear-Lobe and nose with the FDA Code JYS: ear, nose, and throat manual surgical instrument. Class 1 risk.

Richline Group DBA Inverness guarantees that all components of the device, the manufacturing of the device and packaging do not contain natural rubber or any other synthetic derivatives of natural rubber, latex that contact humans.

6701 Nob Hill Road
Tamarac, FL 33321
954-718-3200

US FDA Medical Device Establishment. Registration.

Registration Number	Status	Company Name	Address	Expiration Date
3010892486	Active	DRL MANUFACTURING S.A. Manufacturer	ZONA FRANCA INDUSTRIAL, SAN PEDRO DE MACORIS, SAN PEDRO DE MACORIS 21000 DOMINICAN REPUBLIC	12/31/2024
3006749547	Active	RICHLINE GROUP, INC. Labeler, Distributor and Product owner	6701 NOB HILL RD, TAMARAC, FLORIDA 33321 UNITED STATES	12/31/2024

Owner Operator Number	Listing Number	Product Code	Device Name	Registration Number	Activities
2243569	B042093	JYS	PERFORATOR, EAR-LOBE	3006749547	Specification Developer
2243569	B042093	JYS	PERFORATOR, EAR-LOBE	3010892486	Manufacturer

STERILIZATION/GUARANTEE OF MICROBIAL INTEGRITY OF INVERNESS PRODUCTS

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 Preconditioned 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.

COPIES OF ALL TESTING RESULTS ARE ON FILE AT RICHLINE GROUP, D/B/A INVERNESS CORPORATION 6701 Nob Hill Rod Tamarac FL 33321 US.

Sincerely,

THE RICHLINE GROUP
6701 NOB HILL ROAD
TAMARAC, FL 33321
954-718-3200

Jose Abrams Quality Director.
Managing Director

10/18/2023
Date