



I N S T R U M E N T S

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## *Declaration of Conformity Certificate*

We, Sklar Corporation (Sklar Instruments), ensure and declare with sole responsibility, that our Class I medical devices of below product reference (Country of Origin: Germany or the United States of America) are covered by FDA (U.S. Food & Drug Administration) Certificates to Foreign Government and Technical Documentation meet the provisions of applicable sections of Article 1, Annex VII, Section 3 Council Directive 93/42/EEC (MDD) which apply to them, and further certify that the applicable chemical, physical and/or inspection test data covering the device and/or processes used in this device are in our files and are subject to your examination. These products are classified as a medical device as per Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.

Sklar Corporation (Sklar Instruments) undertakes to develop, implement and maintain a formally-recognized Quality Management System (ISO 13485 and ISO 9001) to ensure continued adequacy and efficacy applicable to below medical devices. Sklar manufacturing plant in which the products are produced is subject to FDA's periodic inspections.

Products reference:

SKLAR INSTRUMENTS & MEDICAL SUPPLIES

General Surgery, Plastic Surgery, Podiatry, Ophthalmic, TAA, Orthopedic, Econo Sterile, Care & Cleaning, Physician, OB/GYN, Dental, Stainless Steelware, Laparoscopic, Female Patient Care, Surgi-OR, Electrosurgical, Merit, OR Protection

Signed: *JoAnne Stephens*  
Director

This 26th DAY OF APRIL 2018



Sklar Instruments  
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United States of America