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eShield® Sterile — REGULATORY COMPLIANCE STATEMENTS

Section I. Products Included

Section updated: 11/18/2022

Item No.	Description
EC2100	eShield® Sterile – Smartphone Size
EC2290	eShield® Sterile – Camera Lens Rings
EC2300	eShield® Sterile – Tablet Size
EC2370	eShield® Sterile – Insertion Sleeve
EC2371	eShield® Sterile – Insertion Sleeve (private label)
EC2400	eShield® Sterile – SLR Camera Size

Section II. Regulatory Certifications

Section updated: 11/18/2022

US Items EC2100, EC2300, & EC2400 are FDA approved, under 510K number K141438.

EU Items EC2100, EC2300, & EC2400 are CE Mark certified, certificate number 38529.

Section III. Sterility

Section updated: 11/18/2022

Items EC2100, EC2300, & EC2400 are terminally sterilized to a Sterility Assurance Level (SAL) of 10^{-6}, using gamma radiation under the VDmax protocol, validated according to AAMI/ISO guidelines per AAMI/ISO 11137-2.

Section IV. Biocompatibility

Section updated: 10/13/2017

Items EC2100, EC2300, & EC2400 were evaluated for cytotoxicity by a method compliant with the requirements specific in ISO 10993-5.

Cytotoxicity, Irritation and Systemic Toxicity tests were performed. The products listed passed all of these tests and are considered non-cytotoxic.

Section V. Chemical Composition (ROHS Compliance)

Section updated: 4/15/2021

These products have been determined to be RoHS Compliant.

None of the components of these products contain any of the restricted substances above the limits allowed in the RoHS Recast Directive, including: Lead, Mercury, Cadmium, Chromium VI, PBDE, PBB.

Section VI. Chemical Composition (REACH Compliance)

Section updated: 11/18/2022

These products are articles, without intended release of a chemical substance, under the Regulation No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (refer to REACH, Article 3(3)).

None are chemical preparations. Therefore, they are not subject to the (pre)-registration or the registration process. They do not require a safety data sheet.

These products, including any article that the products are composed of, do not contain at greater than 0.1% by weight a SVHC (Substance of Very High Concern) substance identified according to Article 59 of REACH. This declaration reflects the substances on the candidate SVHC list, effective June 2022.

Whitney Medical Solutions does not conduct separate testing on its products and relays this statement based solely on compliance information received from its suppliers as of the date this section was updated.

Section VII. Animal Sources and Byproducts

Section updated: 10/13/2017

Product: No animal-based, or animal-sourced materials are used in the manufacture of these products. The manufacturing process and materials in these products exclude the presence of any animal or human-derived material (raw materials and equipment).

Packaging: The packaging for these products uses Tyvek® by DuPont™. According to DuPont™, Tyvek® "may contain up to 500 ppm of tallow derived substances. Processing conditions of the raw materials used in manufacturing the Tyvek® styles 1059B and 1073B meet or exceed the recommended conditions by European Directive 2000/6/EC, European Commission 2011/C 73/01 or ISO 22442-1 Annex C for protection against TSE (Transmissible Spongiform Encephalopathy)/BSE (Bovine Spongiform Encephalopathy). As such, to the best of our knowledge, the Tyvek® styles 1059B and 1073B as manufactured do not contain substances having the risks of transmitting TSE/BSE."

Section VIII. Country of Origin

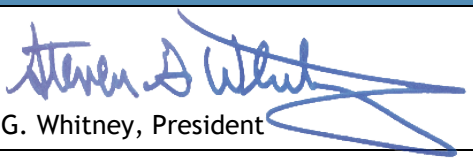
Section updated: 11/18/2022

These products are manufactured in the U.S.A., from materials and components produced in the U.S.A.

Section IX. Approval

Section updated: 11/18/2022

Signed:



Steven G. Whitney, President

Date: 18 November 2022