



SCIENTIFIC PRODUCTS

Bel-Art Products

935 Mearns Road, Warminster, PA 18974 USA

Tel: 973-694-0500 * Fax: 973-694-7199

www.belart.com

CERTIFICATE OF ANALYSIS

This is to verify that all items noted below are in conformance with the Purchase Order Contract, drawings, specifications, and other applicable documentation; that all process certifications, material certifications, are on file at this or another Bel-Art facility and are available for review by the customer and or Government Representatives upon request.

Product #: 36910-0000 Mfg. Date: N/A Lot #: GENERAL

Description: "Sterileware" Sterile Transfer Scoop and Bag 2oz.

Material: High-Impact Polystyrene, Poly bag, sterilized in individual polyethylene bags. Scoop Material meets FDA requirements for regulation 21 part 177.1640. White polystyrene meets FDA regulations 21 CFR 177.1640, 178.3297, 175.300. Sample Bag Material meet FDA regulation 21 CFR 177.1520.

Dimensions: Uses Scoop H36902-0000, 2oz, 17.8cm long, 25mm x 76mm x 38mm (bowl), 4.5" x 9" Resealable Poly Bag 2.5 mil thick, Usable depth approximately 5", Approximate volume 0.125 gallon.

Other: Irradiation exposure dose (avg.)= 23.5- 50.0 kGy. No testing is done for Pyrogens/Endotoxins at this time. AAMI guidelines are followed. Product should remain in its irradiated state as long as outer packaging remains completely intact. Product should be stored in room temperature dry location. Based on the information provided to us this product does not contain or come in contact with Lead, Latex, Melamine, Mercury, Formaldehyde, Nitrosamine or other contaminants. To the best of our knowledge based on information provided to us this product does not contain or come in contact with any animal organ and is BSE/TSE protein free. Materials are RoHS, REACH/SVHC, CPSIA Compliant. There is no expiration for this product.

Manufactured by: Bel-Art Products
2024 Broad Street Pocomoke City, MD 21851
An ISO-9001:2015 facility (certificate US19/819943409)
Made in the USA

Reviewed and Approved By:

Signature: [Handwritten Signature]

Printed Name: Nancy K. Trogani
Title: Technical Support Analyst
Date: 7/8/2024



LIFE SCIENCES BEL-ART

BelArt Products
2024 Broad Street Pocomoke City, MD 21851 USA
Tel: 973-694-0500 * Fax: 973-694-7199
Internet Address: http://www.belart.com

Date: 10/2/2024
Re: Regulatory and Compliance Information
SterileWare (sterile sampling) Products
(36910-0000 STERILEWARE STERILE SCOOP AND BAG,2 OZ)

The following is a non-exhaustive list of these products and their Regulatory and Compliance status.

Signature: [Handwritten Signature]

Michael Grzelak
Technical Support Analyst
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Table with 4 columns: Regulation, Compliant?, Description, non-compliant chemicals. Rows include EU RoHS and EU REACH SVHC.

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Bel-Art | FTS | Genevac | Hotpack | Hull i-Dositecno | Service | VirTis | Wilmad

Regulation	Compliant?	Description	non-compliant chemicals
EU REACH ANNEX XIV	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration do not contain any of the REACH ANNEX XIV Substances referenced in the 59 Annex XIV entries, as updated by ECHA on April 8, 2022	
EU REACH ANNEX XVII	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any of the REACH ANNEX XVII Substances	
(EU) 2019/1021 Persistent Organic Pollutants	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any Persistent Organic Pollutant (EU POP) regulation (EU) 2019/1021 as updated on 9 December, 2022, including, but not limited to, all PFOA and PFOS restrictions listed in Annex I, Part A of the regulation, unless listed in the table below are marked as "Not Compliant" in the EU POP Compliance Status.	
California Proposition 65 Statement	Not compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any of do not contain any of the CA Prop 65 Substances updated on Jan 27, 2023	Styrene CAS# 100-42-5 cancer warning
Per- and Polyfluoroalkyl Substances (PFAS)	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any of the PFAS compounds. For the purpose of this declaration, PFAS chemicals are defined as a class of organic chemicals containing at least one fully fluorinated atom. There are reference lists of known PFAS compounds, however, this statement incorporates all PFAS compounds regardless of their presence on any reference lists.	
Medium-chain chlorinated paraffins (MCCP)	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any of the Medium-chain chlorinated paraffins (MCCP) compounds	
Latex Statement	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any Latex	
Melamine Statement	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any Melamine or related plastics in accordance with Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. Melamine analytical tests have NOT been carried out demonstrating that the articles do not release formaldehyde in a quantity exceeding the SML of 15 mg/kg	
DEHP PHTHALATE-free Statement	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration that our products are not manufactured with or in proximity to any DEHP Phthalate related compounds, and as such there is no chance of any contamination of this type.	
Nitrosamine Statement	compliant	This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration does not contain any Nitrosamine containing compounds	

Regulation	Compliant?	Description	non-compliant chemicals
<p>Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h)</p>	<p>compliant</p>	<p>This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration and as required under the Toxic Substances Control Act (TSCA), our company does not manufacture or handle any of the five newly listed PBT chemicals listed below.</p> <p>Decabromodiphenyl ether (DecaBDE) Phenol, isopropylated phosphate (3:1) (PIP (3:1)) 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) Hexachlorobutadiene (HCBD) Pentachlorothiophenol (PCTP)</p>	
<p>EU MDR (CMR 1A & 1B)</p>	<p>compliant</p>	<p>This is to confirm that this product as shown in this Certificate of Analysis, as of the date of issuance of this Declaration, DOES NOT contain any substance listed in the list of CMR(Carcinogenic, Mutagenic and Reproductive Toxins), of category 1A or 1B, as requested in the Regulation (2017/745).</p>	

DOMINIQUE DUTSCHER SAS



Date: 01/01/2024

Re: Expiration Dates / Sterilization - Sterileware® Product Line

Bel-Art products do not carry expiration dates.

The products remain sterile as long as the barrier remains unbroken preventing bacteria and or other airborne particulates from entering into the sterile item.

It is recommended that the items be properly stored to maintain the packages integrity. Items should be stored in a clean and dry (non-humid) environment at ambient temperature while protected from direct sunlight or harsh chemicals until ready for use.

It is also recommended that the principal processing technique of first in – first out be used while maintaining inventory. Any definitive shelf life should be governed by the end user’s protocol.

Devices are generally regarded as sterile as long as package integrity has not been compromised. Also notable is that the manufacturing and sterilization processes have remained the same since the line’s introduction over 10 years ago.

I certify that I am authorized to declare that the statement made with this Certificate of Compliance is true and accurate.

I certify that I am authorized to declare that this statement is true and accurate.

A handwritten signature in blue ink, appearing to be 'Nancy Trogani', is written over a faint watermark that reads 'DOMINIQUE DUTSCHER SAS'.

Signature: _____

Nancy Trogani

Technical Support Analyst

[Bel-Art](#) | [Wilmad](#) | [Ableware](#)

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