

CERTIFICATE OF COMPLIANCE

DATE: May 29, 2025
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -30, 31, 33, 34, 35, 37
MATERIAL TYPE: T60-800-119 HIGH DENSITY POLYETHYLENE RESIN
SUPPLIER: INEOS (www.ineos.com)

Dear Valued Customer,

Thank you for your interest in Nordson MEDICAL's Value Plastics line of products. As part of our continuous improvement initiatives, and to provide the most timely and effective responses possible, we have created this comprehensive list of the most up to date regulatory compliance information available at <https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Material-Information/> and <https://www.nordsonmedical.com/Resources/Regulatory-Compliance>. The information contained herein generally fulfills the bulk of our customers' regulatory requirements, however if there is additional information required that is not provided here, please submit your request to [LOV_QA- RA@nordsonmedical.com](mailto:LOV_QA-RA@nordsonmedical.com).

Please be informed that Nordson MEDICAL relies on information provided by our suppliers and vendors, whose materials make up the sole content of our products as there are no processing agents or mold releases used in the manufacture of our products. Nordson MEDICAL does not test or analyze these materials for ANY specified regulatory requirements; the information provided by the resin manufacturers has simply been compiled in a readily retrievable format as a service to our customers. Ultimately customers and end-users must make their own determinations ensuring the use of these products is safe, lawful, and suitable for their intended applications. Because of possible changes in the law and/or in regulations, we encourage our customers to periodically verify the status of the regulatory compliance. These compliance letters are typically updated annually, upon receiving new regulatory information, or as deemed necessary.

Regards,

A handwritten signature in black ink, appearing to read "Brian Benton".

Brian Benton
Quality Manager



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USE OF THIS REGULATORY INFORMATION

The information provided as requested is intended to be used for informational purposes only. Nordson MEDICAL relies on information provided by their suppliers or vendors. Nordson MEDICAL makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of compounds under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.

ITEM	REGULATORY REQUIREMENTS	COMPLIANT				COMMENTS
		Y	N	N/A	See Comment	
1	Allergens (Global Food)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
2	Corn / Plant / Vegetable	Y				The supplier of this material has not indicated if this product was manufactured using raw materials of corn/plant origin.
3	ELV Directive 2000/53/EC (Heavy Metal)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

4	21 CFR 177.2510, 177.2600, 177.1520, 21 CFR 178.3297, 21 CFR 176.170, 21 CFR 177.1500, 21 CFR 177.1580, 21 CFR 177.1520(a)(3)(a) and (c) 3.1a, 21 CFR 177.1550, 21 CFR 177.2470, 21 CFR 177.2480, 21 CFR 177.2600, 21 CFR 177.2600 (Food Contact)				See Comment	Under 21 CFR 177.1520©2.2, this resin may be used safely in articles for packaging or holding food during cooking.
5	3-A Sanitary Standards				See Comment	Our Supplier has not indicated if this material meets these standards.
6	AD-DSL (the Aerospace & Defense Declarable)				See Comment	As far as our knowledge this product is Not listed/Not regulated. Although Nordson does not monitor this list closely, Nordson Medical is focused on Medical Compliance especially to the ISO 13485 Standards. The customer is responsible for verifying this information for themselves.
7	Animal Derived Materials	Y				No animal fats, oils, milk products, or other animal or tallow derived products are used as components of, or in the manufacture of this product.
8	Aromatic Amines	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
9	ASTM D3222				See Comment	Our Supplier has not indicated if this material meets these standards.
10	ASTM F963 Standard Consumer Safety for Toy Safety				See Comment	Our Supplier has not indicated if this material meets these standards.
11	Biocides	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
12	Biocompatibility				See Comment	Our Supplier has not indicated if this material meets these standards.
13	Bioterrorism Act of 2002			NA		The facility manufacturing these products not required to register with the Bioterrorism.

14	BISPHENOL A (BPA)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
15	BSE/TSE	Y				This material does not contain any ingredient materials that are animal derived.
16	California Prop 65	Y				No substance listed on California's Proposition 65 chemicals listing, known to the State of California to cause cancer or reproductive toxicity, is intentionally added in the manufacture of this product.
17	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS				See Comment	none of the chemicals on WHMIS, Canada's prohibition of certain toxic substances list or the Canadian Chemical Management Plan are intentionally added as raw materials. Canada's Challenge and Chemical Management Plan: None of the chemicals on either Canada's Prohibition of Certain Toxic Substances list or the Canadian Chemical Management Plan are intentionally added as raw materials to this product. Health Canada, Health Products and Food Branch "No Objection" Letter: A Letter of No Objection (LONO) is not available for this product.
18	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington	Y				This substance is not intentionally used in manufacture or formulation.
19	China RoHS				See Comment	China's Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials (GB 9685-2008): As dispatched from the manufacturer's plant, this material meets the relevant requirements laid down in GB 9685-2008 and its subsequent amendments.
						Under the Clean Air Act, US EPA is required to regulate emissions of hazardous air pollutants (HAPs). This original list included 189 pollutants. Since 1990, EPA has modified

20	Clean Air Act, 40 CFR	Y			the list through rulemaking to include This assessment is based on the 187 substances identified by the EPA as hazardous air pollutants including the general class of glycol ether substances as defined by the Toxic Release Inventory (TRI) (EPA 745-R-00- 004). Based on the final product composition, this product is not known or expected to contain US HAPs as defined by the regulation.
21	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	Y			To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
22	CONEG	Y			The regulated metals – lead, mercury, cadmium, and hexavalent chromium – are not intentionally added during the manufacturing process. Testing for heavy metals – cadmium, chromium, lead, and mercury – resulted in a total for all metals detected of < 2 ppm, compared to the CONEG requirement of <100 ppm. The result for incidental lead concentration was less than the detection limit of .1 ppm.
23	Conflict Minerals	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
24	Consumer Product Safety Improvement Act of 2008 (CPSIA)	Y			This material conforms to the substance limits and prohibition requirements of this regulation.
25	Drug Master File	Y			This material is filed with the FDA in INEOS Drug Master File 1362.
26	Endotoxins	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

27	EU 200/53/EC & 2002/525/EC - END-OF-Life Vehicles Regulation				See Comment	Our Supplier has not indicated if this material meets these standards.
28	EU Commission Decision 2009/251/EC – Dimethyl Fumarate				See Comment	Our Supplier has not indicated if this material meets these standards
29	EU Directive 2002/16/EC				See Comment	Our Supplier has not indicated if this material meets these standards.
30	EU Directive 2003/11/EC				See Comment	Our Supplier has not indicated if this material meets these standards.
31	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromocyclododecane (HBCDD) and Hexachlorobenzene (HCB)				See Comment	Our Supplier has not indicated if this material meets these standards.
32	EU Directive 90/128 and subsequent amendments				See Comment	Our Supplier has not indicated if this material meets these standards.
33	EU MDR				See Comment	Based on review of the final product composition, substances listed in the EU Regulation 2017/745 on medical devices, Chapter II, Section 10.4.1, regarding the absence of substances above 0.1% which are (a) carcinogenic, mutagenic, or toxic to reproduction ("CMR") of category 1A or 1B, and (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health, are not known to be present above the declaration threshold.
34	EU-Food Contact				See Comment	EU Food Contact Compliance – Commission Regulation (EU) No 10/2011: As dispatched from the manufacturer's plant, the monomers and additives of this product meet the requirements of the Commission Regulation (EU) NO 10/2011 as amended under the framework Regulation EU 935/2004.

35	EU-Pharmacopeia (7th Edition)				See Comment	All Additives in this product are specified as approved in European Pharmacopoeia 3.1.3, "Polyolefins".
36	European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste	Y				The regulated metals – lead, mercury, cadmium, and hexavalent chromium – are not intentionally added during the manufacturing process. Testing for heavy metals – cadmium, chromium, lead, and mercury – resulted in a total for all metals detected of < 2 ppm, compared to the CONEG requirement of <100 ppm. The result for incidental lead concentration was less than the detection limit of .1 ppm.
37	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)				See Comment	This regulation does not apply to our product because our products are not manufactured with any of the following substances: A) 2,2- Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, hereinafter referred to as "BADGE" (CAS NO 001675-54-3), and some of its derivatives B) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, hereinafter referred to as BFDGE (CAS NO 039817-09-9) C) other Novolac glycidyl ethers, hereinafter referred to as NOGE.
38	Formaldehyde	Y				Not intentionally added in the manufacturing of or formulation.
39	Genetically Modified Organism Free				see comment	Because of the multitude of crop sources used, our suppliers of plant-based additives are unable to certify that their products are 100% GMO-Free.
40	GHS	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
41	Gluten-Free	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

42	ILFI – Red List Chemicals The International Living Future Institute	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
43	In Vitro Hemocompatibility Assay (ISO)				See Comment	Our Supplier has not indicated if this material meets these standards.
44	International Inventories				See comment	EU – EINECS – YES China – IECSC – YES Canada – DSL – YES Australia – AICS – YES Japan – ENCS – YES- New Zealand – NZIoC – YES Korea – KECI – YES Philippines – PICCS – YES Taiwan – NECI - YES
45	ISO 10993-1				See Comment	Our Supplier has not indicated if this material meets these standards.
46	ISO 10993-10				See Comment	Our Supplier has not indicated if this material meets these standards.
47	ISO 10993-11				See Comment	Our Supplier has not indicated if this material meets these standards.
48	ISO 10993-12				See Comment	Our Supplier has not indicated if this material meets these standards.
49	ISO 10993-18, EXTRACTABLES TESTING				See Comment	Our Supplier has not indicated if this material meets these standards.
50	ISO 10993-2				See Comment	Our Supplier has not indicated if this material meets these standards.
51	ISO 10993-3				See Comment	Our Supplier has not indicated if this material meets these standards.
52	ISO 10993-4				See Comment	Our Supplier has not indicated if this material meets these standards.
53	ISO 10993-5				See Comment	Our Supplier has not indicated if this material meets these standards.
54	ISO 10993-6				See Comment	Our Supplier has not indicated if this material meets these standards.

55	Kosher		N			Supplier does not certify this resin to be Kosher or in compliance with Kosher requirements.
56	Lactose	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
57	Latex	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
58	MA Right to Know Extraordinarily Hazardous Substance List	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
59	Melamine	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
60	Natural Rubber	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
61	Nitrosamines	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
62	NJ Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
63	Nanoparticles	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
64	NSF 61				See Comment	See https://www.nsf.org/certified-products-systems for reference.
65	NSF-14				See Comment	See https://www.nsf.org/certified-products-systems for reference.
66	NSF-51				See Comment	See https://www.nsf.org/certified-products-systems for reference.

67	Other Substance/compounds			see comment	<p>Listed substances/compounds are not intentionally used in manufacture or formulation: Tris (Nonylphenyl) Phosphite (TNPP), Triclosan (2,4,4' – trichloro-2'-hydroxy-diphenyl ether), Solvents, residual solvents, Silicone, Short Chain Chlorinated Paraffins (SCCPs), Radioactive Substances, PVC, Phthalates (BBP, BDP, DBP, DCP, DEHP, DEP, DiDP, DMP, DnHP, DnOP, DiiHP), Per- and Polyfluorinated compounds (PFAS), PCBs, PAHs (Polycyclic Aromatic Hydrocarbons), Ozone Depleting Chemicals (ODCs), Organotin Compounds, Nitrosamines, N-Ethyl-toluenesulfonamide (Ortho/Para), Nanoparticles, Melamine, Materials banned by Lacey Act of 1900, Latex, Jatropa Oil, Genetically Modified Organisms, Formaldehyde, Flame Retardants (Brominated, Phosphorous- or Nitrogen-based, or Chlorinated), Dioxins, Dimethyl Fumarate (DMF), Decabromodiphenyl ether, Conflict Minerals, Heavy Metals, Cocamide diethanolamine, Bisphenols A (BPA) or S (BPS), Benzophenones, Azodicarbonamide, Azo dyes / Colorants / Pigments, Asbestos, Antimicrobial agents / Biocides / Fungicides / Pesticides, Alkyphenols and Ethoxylates, 3-MCPD (3- monochloropropane), Aluminum, cadmium, lead, mercury, cobalt, nickel, chromium, titanium, vanadium, zinc, zirconium.</p>
68	Ozone Depleting Substances	Y			<p>Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.</p>

69	PA Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
70	Persistent Organic Pollutants (POP)	Y				The substances listed in Annex 1 of Regulation (EU) 2019/1021(issued October 31,2024), as amended by Regulation (EU) 2023/1608, substances identified at the Stockholm Convention does not contain in the formulation and are not intentionally added during the manufacturing of the listed molding compound. Due to the absence of use of these substances, we do not evaluate for them.
71	PFAS (Per and Polyfluoroalkyl substances)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
72	PFCA (Perfluoroalkyl carboxylic acid)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
73	PFOA (Perflouroctanoic acid)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
74	PFOS (Perflouroctane sulfonate)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
	Phthalates: Dibutyl phthalate Diethyl phthalate (DEHP) Di-isononyl phthalateDimethyl phthalate DMP CAS# 131-11-3 Diethyl phthalate DEP CAS# 84- 66-2 Diallyl phthalate DAP CAS# 131- 17-9 Di-n-propyl phthalate DPP CAS# 131-16-8 Di-n-butyl phthalate DBP CAS# 84-74-2 Diisobutyl phthalate DIBP CAS# 84-69-5					

75	Butyl cyclohexyl phthalate BCP CAS# 84-64-0 1,2-bis(2-methoxyethyl) ester DMEP CAS# 117-82-8 [bis(2-methoxyethyl) phthalate] Di-n-pentyl phthalate DNPP CAS# 131-18-0 1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3 Dicyclohexyl phthalate DCP CAS# 84-61-7 Butyl benzyl phthalate BBP CAS# 85-68-7 Di-n-hexyl phthalate DnHP CAS# 84-75-3	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
76	REACH	Y				Our supplier confirms that substances defined by Article 57 in Regulation (EC) No. 1907/2006 (REACH) and published on the most current candidate list according to Annex XIV at the ECHA website, SVHC issued January 21, 2025 (cumulative), or chemical substances restricted for specific applications listed in Annex XVII or chemicals listed in the substance of very high concern identification list are neither used as raw materials nor as auxiliary materials in the manufacturing process of this product.
77	RoHS / RoHS 2 / RoHS 3	Y				This product conforms to the RoHS Directive 2011/65/EU & 2015/863-EU and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates. Product has not been analyzed for these substances or compounds; any trace amounts of these substances would not be expected to be above the regulated thresholds.
78	SARA (311,312) Hazard Class				See comment	COMBUSTIBLE DUSTS
79	SARA 313 Regulated Chemicals				See comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.

80	SARA Title III – Section 302 Extremely Hazardous Chemicals:				See comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
81	Transport Classification	Y				Not regulated as hazardous for shipment.
82	TSCA				See Comment	The manufacturer confirms that the materials used in the formulation of this product are listed or considered exempt.
83	Unactivated Partial Thromboplastin Time Assay (ISO)				See Comment	Our Supplier has not indicated if this material meets these standards.
84	US Pharmacopeia Class VI				See Comment	Our Supplier has not indicated if this material meets these standards.
85	USDA				See Comment	Our Supplier has not indicated if this material meets these standards.
86	USP 381 (Elastomeric Closures for injection)				See Comment	Our Supplier has not indicated if this material meets these standards.
87	USP 643 (Total Organic Carbon)				See Comment	Our Supplier has not indicated if this material meets these standards.
88	USP 661				See Comment	Our Supplier has not indicated if this material meets these standards.
89	USP 665 (Single-use systems (SUS) & the risk associated with extractable & leachables (E&L))				See Comment	Our Supplier has not indicated if this material meets these standards.
90	USP 85 (Endotoxin)				See Comment	Our Supplier has not indicated if this material meets these standards.
91	USP 851 (Static Sorption Study of Phenol)				See Comment	Our Supplier has not indicated if this material meets these standards.
92	USP 87 (L929 MEM Elution)				See Comment	Our Supplier has not indicated if this material meets these standards.
93	USP 88				See Comment	Our Supplier has not indicated if this material meets these standards.
94	Volatile Organic Compounds (VOCs)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

95	WEEE	Y			<p>The WEEE Directive 2012/19/EU regulates disposal and recycling of electrical and electronic waste. Compliance with the restrictions of this directive can only be confirmed by the producer of the final product. However, for the abovementioned products the supplier confirms that they do not contain any substances listed in Annex II of this directive (2002/96/EC) as an intentional ingredient.</p>
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