

CERTIFICATE OF COMPLIANCE

DATE: May 27, 2025
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -9024
MATERIAL TYPE: LEXAN HPS1-1H1124 POLYCARBONATE
SUPPLIER: SABIC

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 .

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,



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)				See Comment	Various plant sources may have been used, including palm, soybean and rapeseed oils. Nevertheless, since the derivation processes destroys cellular structures, the non-viable chemical substances used are not expected to contain GMO's, natural rubber latex, Jatropa, Colophony or plant allergens.
2	Corn / Plant / Vegetable	Y				The supplier of this material has indicated this product may have been manufactured using raw materials of 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)			N/A		To the Best of our Knowledge: This material has not been evaluated for compliance with the U.S. Federal Food, Drug and Cosmetics Act or the U.S. Food and Drug Administration regulations listed in Title 21 of the Code of Federal Regulations. Medical and pharmaceutical applications are not considered by these regulations.
5	3-A Sanitary Standards			N/A		This material has not been tested against these standards to our knowledge.
6	AD-DSL (the AeroSpace & Defence 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				See Comment	May contain additives which are based upon material of ovine or bovine origin.
8	Aromatic Amines	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
9	ASTM D3222			N/A		Our Supplier has not indicated if this material meets these standards.
10	ASTM F963 Standard Consumer Safety for Toy Safety			N/A		Our Supplier has not indicated if this material meets these standards.
11	Biocides	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
12	Biocompatibility	Y				Components have been tested by the raw material manufacturer under USP Class VI and ISO 10993 standards LISTED BELOW.

13	Bioterrorism Act of 2002			N/A	The facility manufacturing this product is not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
14	BISPHENOL A (BPA)	Y			This material is manufactured using BPA as a monomeric building block. BPA is consumed during the polymerization process to manufacture polycarbonate. Technically unavoidable trace levels typically less than 100 parts per million may remain in the polymer matrix of all polycarbonate resins. Therefore, the manufacturer expects trace levels of BPA to be present in this material.
15	BSE/TSE			See comment	May contain additives which are based upon material of ovine or bovine origin. These additives are normally incorporated into plastics as lubricants, slip agents, anti-static agents, emulsifiers, antioxidants, or corrosion inhibitors as an important component to achieve certain functional properties required for the end use. Our supplier indicates that these materials are exposed to high temperatures and rigorous chemical reactions exceeding the typical stringent requirements. These conditions are considered to be sufficient to inactivate Genetically Modified Organisms (GMO) &/or Transmissible Spongiform Encephalopathy transmitters.
16	California Prop 65			See comment	With the exception of residual impurities of trace substances (see below) this product does not use in its manufacture or formulation any substances mentioned in CA Proposition 65: - Bisphenol-A (80-05-7) ≤ 100 PPM - Methylene Chloride (75-09-2) ≤ 10 PPM.

17	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y				All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed. This product is not intentionally manufactured or formulated with the Batch Lists of Canadian environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document, except for Bisphenol A (BPA) (CAS# 80-05-7) listed under Batch 2 Challenge Substances. Please be advised that we do not analyze for these specific substances.
18	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington				See Comment	Bisphenol A poly carbonate (100 PPM) CAS-No. 25971-63-5
19	China RoHS	Y				Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.
20	Clean Air Act, 40 CFR	Y				To the best of our knowledge this product is not intentionally manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1993, as amended (58 FR 8136).
21	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	Y				The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.
22	CONEG	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.
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			No restricted substances are intentionally added or expected as process impurities above corresponding 0.1% threshold limits. (.01% for lead).
25	Drug Master File			N/A	To the best of our knowledge this Material is not Listed.
26	Endotoxins			See Comment	Please be aware that Value Plastics does not perform endotoxin or bioburden testing on our components. The vast majority of our components are catalog products, and may be used in many applications, therefore we do not test or analyze our materials for any specified regulatory requirements. Ultimately, we leave it to the end-user to make their own determination that our products are safe and suited for their intended applications. However, our processes are highly automated with minimal operator contact, and our production processes don't involve water, so we believe endotoxin levels on our parts to be low.
27	EU 200/53/EC & 2002/525/EC -END-OF-Life Vehicles Regulation	Y			No restricted substances are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.
28	EU Commission Decision 2009/251/EC – Diméthylfumarate	Y			To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture.
29	EU Directive 2002/16/EC			N/A	Our Supplier has not indicated if this material meets these standards.
30	EU Directive 2003/11/EC			N/A	Our Supplier has not indicated if this material meets these standards.
31	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenzene (HCB) –	Y			Not used in manufacture or formulation of product.

32	EU Directive 90/128 and subsequent amendments			N/A		Our Supplier has not indicated if this material meets these standards.
33	EU MDR	Y				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	The composition of this material has not been assessed for use in contact with food according to the Commission Regulation (EU) 10/2011.
35	EU-Pharmacopeia (7th Edition)			N/A		The European Pharmacopeia does not contain polycarbonate specific requirements.
36	European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste			N/A		Our Supplier has not indicated if this material meets these standards.
37	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)			N/A		Our Supplier has not indicated if this material meets these standards.
38	Formaldehyde	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
39	Genetically Modified Organism Free	Y				Not intentionally added during manufacture or formulation of this product.
40	GHS	Y				This mixture is not classified according to US-GHS.

41	Gluten-Free			See Comment	This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
42	ILFI – Red List Chemicals The International Living Future Institute	Y			Not intentionally added during the manufacture or formulation of this product.
43	In Vitro Hemocompatibility Assay (ISO)		N/A		This material has not be tested against these standards to our knowledge.
44	International Inventories	Y			<p>A "Listed" entry above means all chemical components are on the respective inventory list and/or a qualifying exemption exists for one or more components. A "Not listed" entry above indicates one or more components is restricted from import or manufacture into that country/region. Articles are exempt from registration and are therefore not listed on the national chemical inventories.</p> <p>TSCA (USA): Listed DSL (Canada): Listed EINECS/ELINCS (Europe): Listed ENCS (Japan): Listed IECSC (China): Listed KECL (Korea): Listed PICCS (Philippines): Listed AICS (Australia): Listed</p>
45	ISO 10993-1	Y			<p>A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.</p>
46	ISO 10993-10	Y			<p>A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4.</p>

					Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
47	ISO 10993-11	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
48	ISO 10993-12	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
49	ISO 10993-18, EXTRACTABLES TESTING			N/A	This material has not be tested against these standards to our knowledge.
50	ISO 10993-2	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.

51	ISO 10993-3	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
52	ISO 10993-4	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
53	ISO 10993-5	Y			A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
54	ISO 10993-6			N/A	A sample of this material has been subjected to certain biocompatibility tests described by ISO 10993 "Biological Evaluation of Medical Devices". These tests include: 1. Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Pyrogenicity Test, and 7, Sensitization test. All samples passed each test.
55	Kosher		N		Supplier does not certify this resin to be Kosher or in compliance with

					Kosher requirements.
56	Lactose	Y			Not intentionally added during the manufacture or formulation of this product.
57	Latex	Y			Not used in the manufacture or formulation of this product.
58	MA Right to Know Extraordinarily Hazardous Substance List			See Comment	Methylene Chloride (10 ppm). CAS-No. 75-09-2 Bisphenol A poly carbonate (100 PPM) CAS- No. 25971-63-5.
59	Melamine	Y			Not intentionally used in the manufacture or formulation of this product.
60	Natural Rubber	Y			Not used in the manufacture or formulation of this product.
61	Nitrosamines	Y			Not intentionally added during the manufacture or formulation of this product.
612	NJ Right to Know Regulated Chemicals			See Comment	Bisphenol A poly carbonate (100 PPM) CAS-No. 25971-63-5
63	Nanoparticles	Y			To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
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				<p>The following material and compounds are not intentionally used or added in the formulation or manufacture of this product, but due to the nature of these items we do not test for them:</p> <p>Aflatoxins, Alkylphenols/alkylphenols ethoxylate, Arsenic, Asbestos, Azodyes, Azoxy compounds, Benzotriazole, Beryllium, Beta hydroxy acids (BHA), Butylated hydroxytoluene 9BHT), Bisphenol A (BPS), Brominated compounds, Chlorofluorocarbons, Chlorinated naphthalene, Chlorinated paraffins, Creosote, Copper, Decabromodiphenyl ether (Deca-BDE), Dimethyl Fumarate (DMF), Dioxins, Halogenated Compounds, Hexabomocyclododecane, Iridium, Iron, Isocyanate, Jatropa, Lead, lindane, Melamine, Mercury, Mold Release, Molybdenum, Nickel, Nitrosamines, Nonylphenol-Nonylphenol ethoxylates, Octabromodiphenyl ethers, Organotin compounds, osmium, palladium, parabens, PCB, PCP, Pentabromodiphenyl ethers, Pentachlorophenol, Perchlorate, Platinum, Polycyclic Aromatic Hydrocarbons (PAH), Polybrominated biphenyls (PBB), Polybrominated Diphenyl Ethers (PBDEs), Polychlorinated biphenyls, Polychlorinated dibenzopdioxins/ Polychlorinated dibenzofurans, Polychlorinated Naphthalene (PCN), Polychlorinated Terphenyls (PCT), Polyvinyl Chloride, Polyurethane, Radioactive substances, Red Phosphorus, Rhodium, Rnase, Ruthenium, Silicone oils, TALC, Tin organic compounds, TNPP, toluene,</p>
				See Comment	

					triclosan, tri (2 4-di-tert-butylphenyl) phosphite, Vanadium, Vinyl Chloride, Vinylidene chloride, Xylene, Zinc
68	Ozone Depleting Substances	Y			Not intentionally added during manufacture or formulation of this product.
69	PA Right to Know Regulated Chemicals			See Comment	Bisphenol A poly carbonate (100 PPM) CAS-No. 25971-63-5
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.
71	PFAS (Per and Polyfluoroalkyl substances)	Y			Not intentionally added during the manufacture or formulation of this product.
72	PFCA (Perfluoroalkyl carboxylic acid)	Y			Not intentionally added during the manufacture or formulation of this product.
73	PFOA (Perfluorooctanoic acid)	Y			Not intentionally added during the manufacture or formulation of this product.
74	PFOS (Perfluorooctanoic sulfonate)	Y			Not intentionally added during the manufacture or formulation of this product.

75	<p>Phthalates:</p> <p>Dibutyl phthalate</p> <p>Diethyl phthalate (DEHP)</p> <p>Di-isononyl phthalate</p> <p>Dimethyl phthalate</p> <p>DMP</p> <p>CAS# 131-11-3</p> <p>Diethyl phthalate DEP</p> <p>CAS# 84-66-2</p> <p>Diallyl phthalate DAP</p> <p>CAS# 131-17-9</p> <p>Di-n-propyl phthalate DPP</p> <p>CAS# 131-16-8</p> <p>Di-n-butyl phthalate DBP</p> <p>CAS# 84-74-2</p> <p>Diisobutyl phthalate DIBP</p> <p>CAS# 84-69-5</p> <p>Butyl cyclohexyl phthalate</p> <p>BCP</p> <p>CAS# 84-64-0</p> <p>1,2-bis(2-methoxyethyl) ester</p> <p>DMEP</p> <p>CAS# 117-82-8</p> <p>[bis(2-methoxyethyl) phthalate]</p> <p>Di-n-pentyl phthalate DNPP</p> <p>CAS# 131-18-0</p> <p>1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear</p> <p>CAS# 84779-61-3</p> <p>Dicyclohexyl phthalate DCP</p> <p>CAS# 84-61-7</p> <p>Butyl benzyl phthalate BBP</p> <p>CAS# 85-68-7</p> <p>Di-n-hexyl phthalate DnHP</p> <p>CAS# 84-75-3</p>	Y				Not intentionally added during manufacture or formulation of this product.
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				<p>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 been analyzed for these substances and/or compounds; any trace amounts of these substances would not be expected to be above the regulated threshold limit of 0.1% w/w (each) except Cadmium, which has a threshold of limit of 0.01% w/w.</p>
78	SARA (311,312) Hazard Class	Y				<p>This product is not considered an Acute Health Hazard, a Chronic Health Hazard, a Fire Hazard, a Sudden Release of Pressure Hazard, or a Reactive Hazard.</p>
79	SARA 313 Regulated Chemicals	Y				<p>Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.</p>
80	SARA Title III – Section 302 Extremely Hazardous Chemicals:	Y				<p>AS far as our knowledge this product is Not listed/Not regulated.</p>
81	Transport Classification	Y				<p>Not regulated as hazardous for shipment.</p>
82	TSCA	Y				<p>Listed on the TSCA Inventory. No substances are subject to TSCA 12(b) export notification requirements.</p>
83	Unactivated Partial Thromboplastin Time Assay (ISO)			N/A		<p>This material has not been tested against these standards to our knowledge.</p>
84	US Pharmacopeia Class VI	Y				<p>Samples of this material were subjected to biocompatibility tests specified by the United States Pharmacopeia. The sample passed each of these tests and met the criteria for USP Class VI.</p>

85	USDA			N/A		This material has not been tested against these standards to our knowledge.
86	USP 381 (Elastomeric Closures for injection)			N/A		This material has not been tested against these standards to our knowledge.
87	USP 643 (Total Organic Carbon)			N/A		This material has not been tested against these standards to our knowledge.
88	USP 661			N/A		This material has not been tested against these standards to our knowledge.
89	USP 665 (Single-use systems (SUS) & the risk associated with extractable & leachables (E&L))				N/A	This material has not been tested against these standards to our knowledge.
90	USP 85 (Endotoxin)			N/A		This material has not been tested against these standards to our knowledge.
91	USP 851 (Static Sorption Study of Phenol)				N/A	This material has not been tested against these standards to our knowledge.
92	USP 87 (L929 MEM Elution)			N/A		This material has not been tested against these standards to our knowledge.
93	USP 88			N/A		This material has not been tested against these standards to our knowledge.
94	Volatile Organic Compounds (VOCs)	Y				Not used in the manufacture or formulation of this product.
95	WEEE			N/A		The WEEE-Directive 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. To our best knowledge this product is compliant.