

## CERTIFICATE OF COMPLIANCE

**DATE:** May 13, 2025

**SUBJECT:** REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS

**PART AFFECTED:** ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -9

**MATERIAL TYPE:** MAKROLON 2558 550115 PLOYCARBONATE RESIN

**SUPPLIER:** Covestro <http://www.covestro.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,



**Brian Benton**  
Quality Manager

## CERTIFICATE OF COMPLIANCE

**DATE:** May 13, 2025  
**SUBJECT:** REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS  
**PART AFFECTED:** ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -9  
**MATERIAL TYPE:** MAKROLON 2558 550115 PLOYCARBONATE RESIN  
**SUPPLIER:** Covestro <https://www.covestro.com/>

### 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			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, Jatropha, Colophony, or plant allergens.
2	Plant / Vegetable / Corn	Y				The manufacturer of this material has indicated this product may have been manufactured using raw materials of a 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	<b>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)</b>				See Comment	MAKROLON® 2558 550115 may be used in food contact applications in compliance with FDA regulation 21 CFR § 177.1580 (Polycarbonate resins), for use in contact with all food types under FDA Conditions of Use B through H as described in 21 CFR § 175.300, Tables 1 and 2. MAKROLON 2558 550115 is not permitted for use in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups). The use of MAKROLON 2558 550115 is subject to the limitations of § 177.1580 and any other applicable regulation. MAKROLON 2558 550115 is manufactured under Good Manufacturing Practice in accordance with FDA regulation 21 CFR 174.5 “General provisions applicable to indirect food additives.”
5	<b>3-A Sanitary Standards</b>			N/A		This material has not been tested against these standards to our knowledge.
6	<b>AD-DSL (the AeroSpace &amp; Defence Declarable)</b>				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	<b>Animal Derived Materials</b>				See Comment	Contains a minor quantity of a component that is derived from animal sources.
8	<b>Aromatic Amines</b>	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	<b>ASTM D3222</b>			N/A		Our Supplier has not indicated if this material meets these standards.
10	<b>ASTM F963 Standard Consumer Safety for Toy Safety</b>			N/A		Our Supplier has not indicated if this material meets these standards.
11	<b>Biocides</b>	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	<b>Biocompatibility</b>	Y				Components have been tested by the raw material manufacturer under USP Class VI and ISO 10993 standards LISTED BELOW.
13	<b>Bioterrorism Act of 2002</b>			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	<b>BISPHENOL A (BPA)</b>				See Comment	Residual BPA in polycarbonate resin is generally less than 50 ppm. The BPA level in resin may vary according to design and processing conditions. To determine BPA levels, you will need to test your product.
15	<b>BSE/TSE</b>	Y				<p>Contains substances that are derived from tallow sources. The processing conditions used in the production of these tallow derivative products are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC, Commission Regulation 722/2012 and the Notes for Guidance EMEA/410/01 Rev 3.</p> <p>Process Conditions – Regulation 142/2011 EC Annex XIII Chapter XI:</p> <p>a) Transesterification or hydrolysis at least: 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or</p> <p>b) Saponification with NaOH 12 M (glycerol and soap) in a batch process at 95°C for 3 hours, or in a continuous process at 140°C, 2 bars (2,000 hPa) for 8 minutes; or Hydrogenation at 160°C at 12 bars (12,000 hPa) for 20 minutes.</p> <p>These conditions also meet the requirements of ISO 22442-1:2007 Annex C.5 regarding the processing of tallow derivatives used in medical devices.</p>
16	<b>California Prop 65</b>				See Comment	This product contains chemical(s) known to the State of California to be carcinogenic: <=3 ppm: Methylene Chloride 75-09-2; Trace element: Bisphenol A 80-05-7.

17	<b>Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS</b>	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	<b>Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington</b>				See Comment	Bisphenol A poly carbonate (1%) CAS-No. 25971-63-5.
19	<b>China RoHS</b>	Y				Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.
20	<b>Clean Air Act, 40 CFR</b>	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	<b>Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):</b>	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	<b>CONEG</b>	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	<b>Conflict Minerals</b>	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	<b>Consumer Product Safety Improvement Act of 2008 (CPSIA)</b>	Y				To the best of our knowledge This product is not manufactured or formulated with lead, di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Our supplier has indicated that it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.
25	<b>Drug Master File</b>			N/A		To the best of our knowledge this Material is not Listed.

26	<b>Endotoxins</b>				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	<b>EU 200/53/EC &amp; 2002/525/EC -END-OF-Life Vehicles Regulation</b>	Y				our Supplier indicated this material complies with requirements.
28	<b>EU Commission Decision 2009/251/EC – Dimethylfumarate</b>	Y				To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture.
29	<b>EU Directive 2002/16/EC</b>			N/A		Our Supplier has not indicated if this material meets these standards.
30	<b>EU Directive 2003/11/EC</b>	Y				Our supplier indicated this material meets these standards.
31	<b>EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenze (HCB) –</b>			N/A		Our Supplier has not indicated if this material meets these standards.
32	<b>EU Directive 90/128 and subsequent amendments</b>			N/A		Our Supplier has not indicated if this material meets these standards.
33	<b>EU MDR</b>	Y				Covestro product MAKROLON 2558 550115 complies with the material requirements of 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. The material has been confirmed to meet the ATP20 of the EU Regulation 1272/2008. Also, to the best of our knowledge, this product complies with Commission Regulation 722/2012 regarding medical devices manufactured utilizing tissues of animal origin.

34	<b>EU-Food Contact</b>				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	<b>EU-Pharmacopeia (7th Edition)</b>			N/A		The European Pharmacopeia does not contain polycarbonate specific requirements.
36	<b>European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste</b>			N/A		Our Supplier has not indicated if this material meets these standards.
37	<b>European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)</b>			N/A		Our Supplier has not indicated if this material meets these standards.
38	<b>Formaldehyde</b>	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	<b>Genetically Modified Organism Free</b>				See Comment	Not intentionally added during manufacture or formulation of this product.
40	<b>GHS</b>	Y				This mixture is not classified according to US-GHS.
41	<b>Gluten-Free</b>				See Comment	This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
42	<b>ILFI – Red List Chemicals The International Living Future Institute</b>	Y				Not intentionally added during the manufacture or formulation of this product.
43	<b>In Vitro Hemocompatibility Assay (ISO)</b>			N/A		This material has not been tested against these standards to our knowledge.
44	<b>International Inventories</b>	Y				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. TSCA (USA): Listed DSL (Canada): Listed EINECS/ELINCS (Europe): Listed ENCS (Japan): Listed IECSC (China): Listed KECL (Korea): Listed PICCS (Philippines): Listed AICS (Austria): Listed

45	<b>ISO 10993-1</b>	Y				Certification based upon testing of identical resin with higher level of colorants.
46	<b>ISO 10993-10</b>			N/A		This material has not been tested against these standards to our knowledge.
47	<b>ISO 10993-11</b>			N/A		This material has not been tested against these standards to our knowledge.
48	<b>ISO 10993-12</b>			N/A		This material has not been tested against these standards to our knowledge.
49	<b>ISO 10993-18, EXTRACTABLES TESTING</b>			N/A		This material has not been tested against these standards to our knowledge.
50	<b>ISO 10993-2</b>			N/A		This material has not been tested against these standards to our knowledge.
51	<b>ISO 10993-3</b>			N/A		This material has not been tested against these standards to our knowledge.
52	<b>ISO 10993-4</b>			N/A		This material has not been tested against these standards to our knowledge.
53	<b>ISO 10993-5</b>			N/A		This material has not been tested against these standards to our knowledge.
54	<b>ISO 10993-6</b>			N/A		This material has not been tested against these standards to our knowledge.
55	<b>Kosher</b>		N			Supplier does not certify this resin to be Kosher or in compliance with Kosher Requirements.
56	<b>Lactose</b>	Y				Not intentionally added during the manufacture or formulation of this product.
57	<b>Latex</b>	Y				Not used in the manufacture or formulation of this product.
58	<b>MA Right to Know Extraordinarily Hazardous Substance List</b>				See Comment	Methylene Chloride (<=3 ppm). CAS-No. 75-09-2 Bisphenol A poly carbonate (>=1%) CAS-No. 25971-63-5.
59	<b>Melamine</b>	Y				Not intentionally used in the manufacture or formulation of this product.
60	<b>Natural Rubber</b>	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
61	<b>Nitrosamines</b>	Y				Not used in the manufacture or formulation of this product.
62	<b>NJ Right to Know Regulated Chemicals</b>				See Comment	Bisphenol A poly carbonate (>=1%) CAS-No. 25971-63-5.
63	<b>Nanoparticles</b>	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
64	<b>NSF-61</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.
65	<b>NSF-14</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.



66	NSF-51				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.
67	Other Substance/compounds				See Comment	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: 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 dibenzo- pdioxins/ 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, triclosan, tri (2 4-di-tert-butylphenyl) phosphite, Vanadium, Vinyl Chloride, Vinylidene chloride, Xylene, Zinc
68	Ozone Depleting Substances	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
69	PA Right to Know Regulated Chemicals				See Comment	Bisphenol A poly carbonate (>=1%) CAS-No. 25971-63-5.
70	Persistent Organic Pollutants (POP)	Y				No substances used in the manufacture or formulation of this product that are listed on EC 2019/1021 Annex I as amended are not intentionally used in the manufacture or formulation.

71	<b>PFAS (Per and Polyfluoroalkyl substances)</b>	Y				Not used in the manufacture or formulation of this product.
72	<b>PFCA (Perfluoroalkyl carboxylic acid)</b>	Y				Not used in the manufacture or formulation of this product.
73	<b>PFOA (Perflouroctanoic acid)</b>	Y				Not used in the manufacture or formulation of this product.
74	<b>PFOS (Perflouroctane sulfonate)</b>	Y				Not used in the manufacture or formulation of this product.
75	<b>Phthalates:</b> <b>Dibutyl phthalate</b> <b>Dioctyl phthalate (DEHP)</b> <b>Di-isononyl phthalate</b> <b>Dimethyl phthalate</b> <b>DMP</b> <b>CAS# 131-11-3</b> <b>Diethyl phthalate DEP</b> <b>CAS# 84-66-2</b> <b>Diallyl phthalate DAP</b> <b>CAS# 131-17-9</b> <b>Di-n-propyl phthalate DPP</b> <b>CAS# 131-16-8</b> <b>Di-n-butyl phthalate DBP</b> <b>CAS# 84-74-2</b> <b>Diisobutyl phthalate DIBP</b> <b>CAS# 84-69-5</b> <b>Butyl cyclohexyl phthalate</b> <b>BCP CAS# 84-64-0</b> <b>1,2-bis(2-methoxyethyl) ester</b> <b>DMEP CAS# 117-82-8 [bis(2- methoxyethyl) phthalate]</b> <b>Di-n-pentyl phthalate DNPP</b> <b>CAS# 131-18-0</b> <b>1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear</b> <b>CAS# 84779-61-3</b> <b>Dicyclohexyl phthalate DCP</b> <b>CAS# 84-61-7</b> <b>Butyl benzyl phthalate BBP</b> <b>CAS# 85-68-7</b> <b>Di-n-hexyl phthalate DnHP</b> <b>CAS# 84-75-3</b>	Y				Not intentionally added during the manufacture or formulation of this product.
	<b>REACH</b>	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 Jan 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

76					not intentionally added to this product. This product has not been analyzed for these substances or compounds; however, we would not expect the total of these substances or compounds to be present above the regulated thresholds.
77	<b>RoHS / RoHS 2 / RoHS 3</b>	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	<b>SARA (311,312) Hazard Class</b>	Y			Non-hazardous under Section 311/312 AS far as our knowledge this product is Not listed/Not regulated.
79	<b>SARA 313 Regulated Chemicals</b>	Y			
80	<b>SARA Title III – Section 302 Extremely Hazardous Chemicals:</b>	Y			AS far as our knowledge this product is Not listed/Not regulated.
81	<b>Transport Classification</b>	Y			Not regulated as hazardous for shipment.
82	<b>TSCA</b>	Y			Listed on the Active Portion of the TSCA Inventory. No substances are subject to TSCA 12(b) export notification requirements. This material is not intentionally formulated with any of the following compounds: <ul style="list-style-type: none"> <li>• Decabromodiphenyl ether (DecaBDE)</li> <li>• Phenol, isopropylated phosphate (3:1) (PIP (3:1))</li> <li>• 2,4,6-Tris(tert-butyl) phenol (2,4,6-TTBP)</li> <li>• Hexachlorobutadiene (HCBD)</li> <li>• Pentachlorothiophenol (PCTP)</li> </ul>
83	<b>Unactivated Partial Thromboplastin Time Assay (ISO)</b>			N/A	This material has not been tested against these standards to our knowledge.
84	<b>US Pharmacopoeia Class VI</b>	Y			Certification based upon testing of identical resin with higher level of colorants.
85	<b>USDA</b>			N/A	This material has not been tested against these standards to our knowledge.
86	<b>USP 381 (Elastomeric Closures for injection)</b>			N/A	This material has not been tested against these standards to our knowledge.
87	<b>USP 643 (Total Organic Carbon)</b>			N/A	This material has not been tested against these standards to our knowledge.

88	<b>USP 661</b>			N/A		This material has not been tested against these standards to our knowledge.
89	<b>USP 85 (Endotoxin)</b>			N/A		This material has not been tested against these standards to our knowledge.
90	<b>USP 88</b>			N/A		This material has not been tested against these standards to our knowledge.
91	<b>USP 851 (Static Sorption Study of Phenol)</b>			N/A		This material has not been tested against these standards to our knowledge.
92	<b>USP 87 (L929 MEM Elution)</b>			N/A		This material has not been tested against these standards to our knowledge.
93	<b>USP 665</b>			N/A		This material has not been tested against these standards.
94	<b>Volatile Organic Compounds (VOCs)</b>	Y				Not used in the manufacture or formulation of this product.
95	<b>WEEE</b>			N/A		The WEEE-Directive – (EU) 2024/884 (WEEE) regulates disposal and recycling of electrical and electronic waste. Our Supplier does not intentionally use any heavy metals in the manufacture or formulation of this product. Compliance with the restrictions of this directive can only be confirmed by the producer of the final product.