

## CERTIFICATE OF COMPLIANCE

**DATE:** August 27, 2025

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

**PART AFFECTED:** ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -6005

**MATERIAL TYPE:** P5M6K-080 ANIMAL FREE POLYPROPYLENE RESIN

**SUPPLIER:** INVISTA Polypropylene P5M6K-080

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://fluid-components.nordsonmedical.com/Resources/Resource-Library/>. 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

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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				The comments below are mostly summaries of supplier compliance statements. Detailed supplier's statements available upon request.  Not used in the manufacture or formulation of this product.
2	Plant / Vegetable / Corn	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades.
3	ELV Directive 2000/53/EC (Heavy Metal)	Y				The quantity of Pb, Hg, Cd, and Cr present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2002/525/EC of June 27th (amending Annex II of Directive 2000/53) which establishes: 0.1% Pb, 0.1% Cr, 0.1% Hg, And 0.01% Cd.

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	This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. This conformance includes all ingredients used in the product formulation. These ingredients are compliant to their specific regulations and 21 CFR 177.1520(b). This product can be used for food contact applications with food types I, II, IV-B, VI, VII-B, and VIII of Table 1 and under conditions of use C through H of Table 2 in 21 CFR 176.170(c).
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; Defense 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>	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.
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>	Y				Not used in the manufacture or formulation of this product.
15	<b>BSE/TSE</b>	Y				No tallow or any other animal derived materials used in manufacture or formulation of product.
16	<b>California Prop 65</b>	Y				Based on available information this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65. Reformulation, use, or processing of this material may affect its composition and require re-evaluation.
17	<b>Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS</b>	Y				AS far as our knowledge this product is Not listed/Not regulated.
18	<b>Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington</b>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
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.
	<b>CONEG</b>	Y				Not intentionally added in the manufacturing of or formulation.

22					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>	Y			Listed #9988
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; 002/525/EC END-OF-Life Vehicles Regulation</b>			N/A	Our Supplier has not indicated if this material meets these standards.
28	<b>EU Commission Decision 2009/251/EC – Dimethyl Fumarate</b>	Y			To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture.
	<b>EU Directive 2002/16/EC</b>	Y			This product conforms to the European Directive 2002/16/EC and its amendment 2004/13/EC. We do not use 2,2bis (4- hydroxyphenyl) propane bis (2,3- epoxypropyl) ether (BADGE), Is (hydroxyphenyl)methane bis

29					(2,3- epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product. We do not test this product for these substances.
30	<b>EU Directive 2003/11/EC</b>	Y			This product conforms to the European Directive 2003/11/EC of 6 February 2003 amending 76/769/EEC of 27 July 1976. We do not use Polychlorinated biphenyls (PCB), polychlorinated terphenyls (PCT), Vinyl Chloride, Pentabromide-diphenyl ethers (pentaBDE), Octabromidediphenyl ethers (OctaBDE), or Deca Bromo-diphenyl ethers (DecaBDE) in the manufacture or formulation of this product. We do not test this product for these substances.
31	<b>EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromide cyclooctane (HBCDD) and Hexachlorobenzene (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			Our Supplier does not intentionally use any substances classified as carcinogenic, mutagenic, toxic for reproduction (CMR 1A/1B), or endocrine disrupting substances (EDS) in amounts over 0.1%w/w in the formulation of P5M6K-080. This product does not test each raw material or product we produce for these substances.
34	<b>EU-Food Contact (EC) No 1935/2004</b>		N		This material does not meet the requirements of Regulation 10/2011 for food contact as it contains an additive not present in Annex I. This additive is proprietary and non- disclosed by the supplier.
35	<b>EU-Pharmacopeia (7th Edition)</b>		N		This product does not pass EP 3.1.6 - Polypropylene for Containers for Parenteral Preparations due to the type and/or amounts of additives in this product's formulation. The resin does pass all other testing criteria set in EP 3.1.6.

36	<b>European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste</b>	Y				This product conforms to the European Commission Directive 2004/12/EC of 11 February 2004 amending Directive 94/62/EC on packaging and packaging waste. We recommend proper recycling of plastics as opposed to dumping plastic products into landfills. This product is recyclable according to the recycle code 5.
37	<b>European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)</b>	Y				The manufacturer does not intentionally use 2,2-is(4hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the formulation of this product. We do not test this product for these substances.
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	This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
40	<b>GHS</b>	Y				Meets the requirements for classification and labeling as hazardous under GHS requirements.
41	<b>Gluten-Free</b>	Y				Not intentionally added during the manufacture or formulation of this product.
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				AS far as our knowledge this product is Not listed/Not regulated.
45	<b>ISO 10993-1</b>			N/A		This material has not been tested against these standards to our knowledge.
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>	Y				The requirements for this test were met.
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>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
59	<b>Melamine</b>	Y				Not intentionally used in the manufacture or formulation of this product.
60	<b>Natural Rubber</b>	Y				Not intentionally added during the manufacture or formulation of this product.
61	<b>Nitrosamines</b>	Y				Not intentionally added during the manufacture or formulation of this product.
62	<b>NJ Right to Know Regulated Chemicals</b>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.



63	<b>Nanoparticles</b>	Y				Not intentionally added during the manufacture or formulation of this product.
64	<b>NSF-61</b>				See comment	See <a href="https://www.nsf.org/certifiedproducts-systems">https://www.nsf.org/certifiedproducts-systems</a> for reference.
65	<b>NSF-14</b>				See Comment	See <a href="https://www.nsf.org/certifiedproducts-systems">https://www.nsf.org/certifiedproducts-systems</a> for reference.
66	<b>NSF-51</b>				See Comment	See <a href="https://www.nsf.org/certifiedproducts-systems">https://www.nsf.org/certifiedproducts-systems</a> for reference.
67	<b>Other Substance/compounds</b>				See Comment	<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, Anodynes, Azoxy compounds, Benzotriazole, Beryllium, Beta hydroxy acids (BHA), Butylated hydroxytoluene 9BHT), Bisphenol A (BPS), Bisphenol B, Bisphenol F, Bisphenol AF, Brominated compounds, Chlorofluorocarbons, Chlorinated naphthalene, Chlorinated paraffins, Creosote, Copper, Decabromodiphenyl ether (Deca-BDE), Dimethyl Fumarate (DMF), Dioxins, Halogenated Compounds, Hexabromocyclododecane, Iridium, Iron, Isocyanate, Jatropa, Lead, lindane, Melamine, Mercury, Mold Release, Molybdenum, Nickel, Nitrosamines, Nonylphenol-Nonylpohenol ethoxylates, Octabromodiphenyl ethers, Organotion 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</p>

					<p>Terphenyls (PCT), Polyvinyl Chloride, Polyninylphthalate, 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, Vinylidenechloride, Xylene, Zinc, natural rubber latex, dry natural rubber, synthetic latex, rubber that contains natural rubber, Tin, Tantalum, Tungsten, Gold, Cobalt, Natural Mica, Asbestos, Bisphenol A (BPA), Bisphenol S (BPS), Butylated Hydroxyanisole (BHA), Butylated Hydroxytoluene (BHT), Dimethyl Fumarate (DMF), Triclosan, Trisnonylphenol Phosphite (TNPP), Melamine, Per- and polyfluoroalkyl substances (PFAS) or any other fluorinated compounds, Perfluorooctanoic Acid (PFOA), Perfluoro octane Sulfonate (PFOS), Polyvinyl Chloride (PVC), Vinylidene chloride, Alkylphenols (nonyl- or octyl-) or Alkylphenol ethoxylates (nonyl- or octyl-), Phthalates, Nitrosamines, Dioxins, Polycyclic Aromatic Hydrocarbons (PAH), Polybrominated Biphenyls (PBB's), Polychlorinated Biphenyls (PCB's), Polybrominated Diphenyl Ethers (PBDE's), Polybrominated Terphenyls (PBT's), Polychlorinated Terphenyls (PCT's), Brominated compounds, Tributyl-tin (TBT), Dibutyl-tin (DBT), Monobutyltin (MBT) or any other Organotin compounds.</p>
68	<b>Ozone Depleting Substances</b>	Y			<p>Supplier does not use Class I or Class II ODCs listed by the EPA or in the Resolution 2037/2000/EC in the manufacture or formulation of this product.</p>
69	<b>PA Right to Know Regulated Chemicals</b>	Y			<p>To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.</p>

70	<b>Persistent Organic Pollutants (POP)</b>	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	<b>PFAS (Per and Polyfluoroalkyl substances)</b>	Y				Not intentionally added during the manufacture or formulation of this product.
72	<b>PFCA (Perfluoroalkyl carboxylic acid)</b>	Y				Not intentionally added during the manufacture or formulation of this product.
73	<b>PFOA (perfluorooctanoic acid)</b>	Y				Not intentionally added during the manufacture or formulation of this product.
74	<b>PFOS (Perfluorooctanoate sulfonate)</b>	Y				Not intentionally added during the manufacture or formulation of this product.
75	<b>Phthalates:</b> Dibutyl phthalate Dioctyl phthalate (DEHP) Di-isononyl phthalate Dimethyl 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 Butyl cyclohexyl phthalate BCP CAS# 84-64-0 1,2-bis (2-methoxyethyl) ester DMEP CAS# 117-82-8 [bis(2methoxyethyl) phthalate] Di-n-pentyl phthalate DNPP CAS# 131-18-01,2- Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3	Y				No Phthalates are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.

	<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>					
76	<b>REACH</b>	Y				<p>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 June 25, 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 resin product.</p>
77	<b>RoHS / RoHS 2 / RoHS 3</b>	Y				<p>This product conforms to the RoHS Directive 2011/65/EU &amp; 2015/863-EU and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates.</p>
78	<b>SARA (311,312) Hazard Class</b>	Y				<p>AS far as our knowledge this product is Not listed/Not regulated.</p>
79	<b>SARA 313 Regulated Chemicals</b>	Y				<p>AS far as our knowledge this product is Not listed/Not regulated.</p>
80	<b>SARA Title III – Section 302 Extremely Hazardous Chemicals:</b>	Y				<p>AS far as our knowledge this product is Not listed/Not regulated.</p>
81	<b>Transport Classification</b>	Y				<p>Not regulated as hazardous for shipment.</p>
82	<b>TSCA</b>	Y				<p>Not listed/Not regulated.</p>
83	<b>Unactivated Partial Thromboplastin Time Assay (ISO)</b>			N/A		<p>This material has not been tested against these standards to our knowledge.</p>
84	<b>US Pharmacopeia Class VI</b>	Y				<p>A sample of this material has been tested by the supplier in accordance with USP CLASS VI (USP &lt;85&gt;, USP&lt;88&gt;, Biological Reactivity Tests, In Vivo), and ISO 10993 – 5 standards. Additional information is available upon request.</p>

85	<b>USDA</b>			N/A		This material has not been tested against these standards to our knowledge.
86	<b>USP 85 (Endotoxin)</b>	Y				Supplier has certified Endotoxin (USP<85>) testing has also been performed.
87	<b>USP 87 (L929 MEM Elution)</b>			N/A		This material has not been tested against these standards to our knowledge.
88	<b>USP 88</b>	Y				Supplier has certified biological in vivo (USP<88>) testing has also been performed.
89	<b>USP 381 (Elastomeric Closures for injection)</b>					This material has not been tested against these standards to our knowledge.
90	<b>USP 643 (Total Organic Carbon)</b>					This material has not been tested against these standards to our knowledge.
91	<b>USP 661</b>			N/A		A sample was tested in accordance with USP <661>. Under the conditions of this test, the test results met the USP limits. Additional information is available upon request.
92	<b>USP 665 (Single-use systems (SUS) &amp; the risk associated with extractable &amp; leachables (E&amp;L)</b>					This material has not been tested against these standards to our knowledge.
93	<b>USP 851 (Static Sorption Study of Phenol)</b>			N/A		This material has not been tested against these standards to our knowledge.
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 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.