

## CERTIFICATE OF COMPLIANCE

**DATE:** August 27, 2025  
**SUBJECT:** REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS  
**PART AFFECTED:** ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -PK5  
**MATERIAL TYPE:** Polyketone CS1826-CS8B382PK (M330F PRECO)  
**SUPPLIER:** Hyosun

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 manufacturer does not intentionally use allergens in the formulation of this product.
2	Corn / Plant / Vegetable	Y				The supplier of this material has not indicated if this product was manufactured using raw material or of corn/plant/vegetable 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	<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				Per the manufacturer, this product is made solely from synthetic Plastic polymers. These products are free from known Bovine Spongiform Encephalopathy (BSE) and Transmittable Spongiform Encephalopathy (TSE) causing agents.
16	<b>California Prop 65</b>	Y				No known chemicals are present which are known to the State of California to cause cancer, birth defects, or any other harm.

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.
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				No restricted substances are intentionally added or expected as process impurities above corresponding 0.1% threshold limits. (.01% for lead).
25	<b>Drug Master File</b>			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			N/A		Our Supplier has not indicated if this material meets these standards.
28	EU Commission Decision 2009/251/EC – Dimethyl fumarate	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 - Hexabromidecyclooctane (HBCDD) and Hexachlorobenzene (HCB)			N/A		Our Supplier has not indicated if this material meets these standards.
32	EU Directive 90/128 and subsequent amendments			N/A		Our Supplier has not indicated if this material meets these standards.
33	EU MDR			N/A		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 present.

34	<b>EU-Food Contact (EC) No 1935/2004</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		Our Supplier has not indicated if this material meets these standards.
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>					This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
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				As far as our knowledge this product is Not listed/Not regulated.
45	<b>ISO 10993-1</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
46	<b>ISO 10993-10</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
47	<b>ISO 10993-11</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
48	<b>ISO 10993-12</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.

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>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
51	<b>ISO 10993-3</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
52	<b>ISO 10993-4</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
53	<b>ISO 10993-5</b>	Y				This material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
54	<b>ISO 10993-6</b>			N/A		This material has not be 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 used in 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				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	<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: Aflatoxins, Alkylphenols/alkylphenols ethoxylate, Arsenic, Asbestos, Anodynes, 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, Hexabromocyclododecane, 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</p>

68	<b>Ozone Depleting Substances</b>	Y			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.
69	<b>PA 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.
70	<b>Persistent Organic Pollutants (POP)</b>	Y			To the best of our knowledge, 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> <b>Dibutyl phthalate</b> <b>Dioctyl phthalate (DEHP)</b> <b>Di-isononyl phthalate</b> <b>Dimethyl phthalate 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>Di isobutyl 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</b> <b>CAS# 117-82-8 [bis(2-</b> <b>methoxyethyl) phthalate]</b> <b>Di-n-pentyl phthalate DNPP</b> <b>CAS# 131-18-0</b> <b>1,2-Benzenedicarboxylic acid,</b> <b>dipentyl ester branched and</b> <b>linear</b> <b>CAS# 84779-61-3</b> <b>Di cyclohexyl 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				<p>No Phthalates are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.</p>
76	<b>REACH</b>	Y				<p>To the best of our knowledge, 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 product.</p>

77	<b>RoHS / RoHS 2 / RoHS 3</b>	Y				The supplier of this raw material confirms that the above listed products do not contain any of the 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 manufacturing process of this product.
78	<b>SARA (311,312) Hazard Class</b>	Y				AS far as our knowledge this product is Not listed/Not regulated.
79	<b>SARA 313 Regulated Chemicals</b>	Y				AS far as our knowledge this product is Not listed/Not regulated.
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 listed/Not regulated.
82	<b>TSCA</b>	Y				Components are listed or considered exempt.
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 Pharmacopeia Class VI</b>	Y				This material has been tested and has met the biocompatibility and physiochemical testing requirements according to USP Plastics Class VI.
85	<b>USDA</b>			N/A		This material has not been tested against these standards to our knowledge.
86	<b>USP 85 (Endotoxin)</b>			N/A		This material has not been tested against these standards to our knowledge.
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>			N/A		This material has not been tested against these standards to our knowledge.
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>			N/A		This material has not been tested against these standards to our knowledge.
91	<b>USP 661</b>			N/A		This material has not been tested against these standards to our knowledge.
92	<b>USP 665 (Single-use systems (SUS) &amp; the risk associated with extractable &amp; leachables (E&amp;L))</b>			N/A		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. To our best knowledge this product is compliant.