

CERTIFICATE OF COMPLIANCE

DATE: August 28, 2025
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTCS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH PREFIX SCV
MATERIAL TYPE: VARIOUS
SUPPLIER: VARIOUS

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
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CERTIFICATE OF COMPLIANCE

DATE: August 28, 2025
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTCS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX SCV-
MATERIAL TYPE: VARIOUS
SUPPLIER: VARIOUS

USE OF THIS REGULATORY INFORMATION						
<p>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.</p>						
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 plant origin.
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	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		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 & Defense Declarable)				See Comment	As far as our knowledge this product is Not listed/Not regulated. Although Nordson does not monitor this list closely, Nordson Medical is focused on Medical Compliance especially to the ISO 13485 Standards. The customer is responsible for verifying this information for themselves.
7	Animal Derived Materials				See comment	Our suppliers believe that all raw materials currently used in the material are either not manufactured from animal derived substances, or, if animal-derived, are from animal raw material obtained from suppliers who certify that their products are produced according to regulations and guidelines.
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 these products not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
14	BISPHENOL A (BPA)	Y			Not used in the manufacture or formulation of this product.
15	BSE/TSE	Y			Our suppliers believes that all raw materials currently used in the material are either not manufactured from animal derived substances, or, if animal-derived, are from animal raw material obtained from suppliers who certify that their products are produced according to regulations and guidelines.
16	California Prop 65	Y			Raw materials used to produce these products are in compliance with the Safe Drinking Water and Toxic Enforcement Act of 1986, known as California Proposition 65, in the latest published status. According to the material manufacturers, a few of the used materials contain traces of substances listed in the California Proposition 65. The material manufacturers point out that the very low levels do not represent a significant risk to the user. Affected materials will be communicated upon further request.
17	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y			As far as our knowledge this product is Not listed/Not regulated.

18	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
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 or 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				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	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 – 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	Y				Meets these requirements.
31	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromocyclododecane (HBCDD) and Hexachlorobenzene (HCB)	Y				Meets these requirements.
32	EU Directive 90/128 and subsequent amendments			N/ A		Our Supplier has not indicated if this material meets these standards.

33	EU MDR			See Comment	Based on review of the final product composition, the supplier confirms that according to our assessment and best knowledge all products do not contain substances to EU MDR (section 10.4.1) amounting to more than 0.1% by weight. <i>a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council 1, or (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein. [...] 2 Substances referred to EU MDR section 10.4.1, whose presence affects medical devices compliance status according to ATP 22nd list (CMR 1A, 1B), are not used in any product.</i>
34	EU-Food Contact (EC) No 1935/2004			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		Our Supplier has not indicated if this material meets these standards.
36	European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste	Y			Meets these requirements.

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				The materials used for these products are not derived from plant sources and, therefore, they do not contain genetically modified organisms (GMOs) or recombinant DNA technology.
40	GHS	Y				This mixture is not classified according to US-GHS.
41	Gluten-Free	Y				The materials used for these products are not derived from plant sources and, therefore, they do not contain genetically modified organisms (GMOs) or recombinant DNA technology.
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 been tested against these standards to our knowledge.

44	International Inventories				See Comment	<p>GADSL In the manufacture of the product no substances mentioned in Global Automotive Declarable Substance List (GADSL, www.gadsl.org, GADSL Version 1, released Feb 2010) are used as additives or ingredients or the concentration is below the limits mentioned in the list respectively.</p> <p>JIG In the manufacture of the product no substances mentioned in JOINT INDUSTRY GUIDE (JIG) Material Composition Declaration for Electrotechnical Products JIG-101 Ed 2.0 (Revision of JIG-101A, September 2007) April 28, 2009 are used as additives or ingredients or the concentration is below the limits mentioned in the list respectively.</p> <p>Japanese Control Law In the manufacture of the product no substances mentioned in Japanese Substance Control law (CSCL) Class 1 + 2 http://www.safe.nite.go.jp/english/sougou/view/IntrmSrchSpecifyList_en.faces) are used as additives or ingredients or the concentration is below the limits mentioned in the list respectively.</p>
45	ISO 10993-1			N/A		This material has not been tested against these standards to our knowledge.
46	ISO 10993-10	Y				The requirements for this test were met.
47	ISO 10993-11	Y				The requirements for this test were met.
48	ISO 10993-12			N/A		This material has not been tested against these standards to our knowledge.
49	ISO 10993-18, EXTRACTABLES TESTING			N/A		This material has not been tested against these standards to our knowledge.
50	ISO 10993-2			N/A		This material has not been tested against these standards to our knowledge.
51	ISO 10993-3			N/A		This material has not been tested against these standards to our knowledge.
52	ISO 10993-4	Y				The requirements for this test were met.

53	ISO 10993-5	Y				The requirements for this test were met.
54	ISO 10993-6	Y				The requirements for this test were met.
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 intentionally added during the manufacture or formulation of this product.
58	MA Right to Know Extraordinarily Hazardous Substance List	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
59	Melamine	Y				Not intentionally used in the manufacture or formulation of this product.
60	Natural Rubber	Y				Not intentionally added during the manufacture or formulation of this product.
61	Nitrosamines	Y				Not used in the manufacture or formulation of this product.
62	NJ Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
63	Nonaparticles	Y				The manufacturer confirms that these products do not contain nanomaterials as per the definition provided by the "Commission Recommendation of 18 October 2011 on the definition of nanomaterial", 2011/696/EU.
64	NSF 61				See Comment	See https://www.nsf.org/certified-products- systems for reference .
65	NSF-14				See Comment	See https://www.nsf.org/certified-products- systems for reference .
66	NSF-51				See Comment	See https://www.nsf.org/certified-products- systems for reference .

67	Other Substance / Compounds			See Comment	<p>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, Hexabromocyclododecane, Iridium, Iron, Isocyanate, Jatropha, 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>
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68	Ozone Depleting Substances	Y				The manufacturer confirms that these products comply with the requirements of Regulation (EC) 1005/2009 on substance, that deplete the ozone layer.
69	PA Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
70	Persistent Organic Pollutants (POP)	Y				The European Union implements the obligation of the Stockholm Convention through EU Regulation 2019/1021 on persistent organic pollutants. To the best of our current knowledge, the substances listed in Annex I of Regulation (EU) 2019/1021 as amended by Regulation (EU) 2023/1608 are not used as additives or ingredients in the manufacture of our products.
71	PFAS (Per and Polyfluoroalkyl substances)	Y				Not used in manufacture or formulation of product.
72	PFCA (Perfluoroalkyl carboxylic acid)	Y				Not used in manufacture or formulation of product.
73	PFOA (Perfluorooctanoic acid)	Y				Not used in manufacture or formulation of product.
74	PFOS (Perfluorooctanoic sulfonate)	Y				Not used in manufacture or formulation of product.

75	<p>Phthalates: 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(2-methoxyethyl) phthalate] Di-n-pentyl phthalate DNPP CAS# 131-18-0 1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3 Dicyclohexyl phthalate DCP CAS# 84-61-7 Butyl benzyl phthalate BBP CAS# 85-68-7 Di-n-hexyl phthalate DnHP CAS# 84-75-3</p>	Y			<p>No Phthalates are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.</p>
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76	REACH	Y				Our products and their packaging do not contain any substances of very high concern (SVHC) amounting to more than 0.1% by weight according to the Candidate List of substances of very high concern for Authorization currently published by the ECHA on 2025-06-25. Also, our products and their packaging do not contain any substances of the REACH Annex XIV and Annex XVII.
77	RoHS / RoHS 2 / RoHS 3	Y				As defined in the RoHS Directive 2011/65/EU & 2015/863-EU and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates. Based on a review of the final product composition, there are no RoHS substances known to be present above the reporting threshold.
78	SARA (311,312) Hazard Class	Y				As far as our knowledge this product is Not listed/ Not regulated.
79	SARA 313 Regulated Chemicals	Y				This product is not regulated under section 313 Title III of the Superfund Amendments & Reauthorization Act of 1986.
80	SARA Title III – Section 302 Extremely Hazardous Chemicals:	Y				AS far as our knowledge this product is Not listed/ Not regulated.
81	Transport Classification	Y				Not regulated as hazardous for shipment.
82	TSCA	Y				This material or its components are listed on or are in compliance with the requirements of the TSCA Chemical Substance Inventory. This material or its components are listed on or are in compliance with the requirements of the TSCA Chemical Substance Inventory.
83	Unactivated Partial Thromboplastin Time Assay (ISO)			N/A		This material has not been tested against these standards to our knowledge.

84	US Pharmacopeia Class VI	Y				The components have been tested and certified to be in compliance with the criteria of the US Pharmacopeia, Class VI Section <87> and <88> Biological activity Test, In Vitro and In Vivo.
85	USDA	Y				Components are listed or considered exempt.
86	USP 85 (Endotoxin)			N/A		This material has not been tested against these standards to our knowledge.
87	USP 87 (L929 MEM Elution)			N/A		This material has not been tested against these standards to our knowledge.
88	USP 88			N/A		This material has not been tested against these standards to our knowledge.
89	USP 381 (Elastomeric Closures For Injection)			N/A		This material has not been tested against these standards to our knowledge.
90	USP 643 (Total Organic Carbon)			N/A		This material has not been tested against these standards to our knowledge.
91	USP 661			N/A		This material has not been tested against these standards to our knowledge.
92	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.
93	USP 851 (Static Sorption Study of Phenol)					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.