

CERTIFICATE OF COMPLIANCE

DATE: August 14, 2026
SUBJECT: **REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS**
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -8003
MATERIAL TYPE: TERLUX 2802 TR ABS RESIN
SUPPLIER: INEOS Styrolution (ineos-styrolution.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://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,

A handwritten signature in black ink, appearing to read 'Brian Benton'.

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				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
2	Corn / Plant / Vegetable	Y				Please note that we are unable to confirm that above mentioned product(s) is free of plant derived substances. One or more of the additives used in its/their production can be made from raw materials using either an animal or plant source.
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)				See Comment	Our Supplier has not indicated if this material meets these standards.
5	3-A Sanitary Standards				See Comment	Our Supplier has not indicated if this material meets these standards.
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 Supplier has indicated that the primary components of this resin are petrochemical in nature, not from cattle, sheep, or goat. If additives of animal origin are used, they are treated at high temperatures and undergo chemical reactions, which exceed by far the stringent requirements.
8	Aromatic Amines	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.
9	ASTM D3222				See Comment	Our Supplier has not indicated if this material meets these standards.
10	ASTM F963 Standard Consumer Safety for Toy Safety				See Comment	Our Supplier has not indicated if this material meets these standards.
11	Biocides	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.
12	Biocompatibility				See Comment	Our Supplier has not indicated if this material meets these standards.
13	Bioterrorism Act of 2002	Y				The facility manufacturing these products not required to register with the Bioterrorism.
14	BISPHENOL A (BPA)	Y				Not used in the manufacture or formulation of this product.

15	BSE/TSE	Y			Our Supplier has indicated that all raw materials currently used in the manufacture of the above INEOS Styrolution product(s) are either not manufactured from animal derived substances, or, if animal-derived, originate from Category 3 materials or raw materials, which undergo rigorous production process as described in Annex XIII, Chapter XI of Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009 and consequently, fulfilling the requirements of EMA/410/01 Rev.3 (2011/C 73/01), Chapter 6.4. This process involves using high temperatures (>200°C), under pressure and for more than 20 minutes. Tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk. In conclusion, such tallow derivatives are also exempt from requirements from Commission Regulation (EU) No 722/2012 as defined in Article 1(4) therein (see also Annex I 3 in the regulation).
16	California Prop 65	Y			Please be advised that the above product(s) contain(s) substances which are listed in the safe drinking water and toxic enforcement act of 1986 edited by the Environmental Protection Agency of the State of California. The substances are styrene, acrylonitrile, ethylbenzene, 1,3-butadiene and 4-vinylcyclohexene. We have no information to suggest that exposure to the low levels of above-mentioned substances found in the resins poses any significant risk to the end-user or consumer. There is the potential for another substance that is known to the State of California to be a carcinogen which may be present in trace quantities. This substance is cumene (isopropylbenzene). Though we do not routinely measure for this, the levels are expected to be very low. Many substances are ubiquitous. To the best of our knowledge, the product supplied to you does not contain the above-mentioned substances in concentrations above 0.01 %.

17	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y				All ingredients of this product are listed on the DSL Domestic Substances List or are not required to be listed on the DSL Domestic Substances List.
18	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
19	China RoHS				See Comment	Our Supplier has not indicated if this material meets these standards.
20	Clean Air Act, 40 CFR				See Comment	Methyl methacrylate: Clean Air Act: Hazardous Air Pollutants: yes SOCM Chemical: yes Clean Water Act: Hazardous Substances: RQ 1000 lbs. 1,3- Butadiene: Accidental Release Prevention: Threshold 10000 lbs. / Basis for listing = f Hazardous Air Pollutants: yes SOCMI Chemical: yes Acrylonitrile: Clean Water Act: Hazardous Substances: RQ 100 lbs. Priority Pollutant: yes Styrene: Clean Air Act: Hazardous Air Pollutants: yes SOCMI Chemical: yes
21	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):				See Comment	Styrene: CERCLA: RQ 1000 lbs. Acrylonitrile: CERCLA: RQ 100 lbs 1,3- Butadiene: CERCLA: RQ 10 lbs Methyl methacrylate: Hazardous Substances: RQ 1000 lbs.
22	CONEG	Y				Our supplier has indicated that none of the substances indicated in the 1998 revision of the "The Model Toxics in Packaging Legislation" are used in the formulation of manufacture of this material. These substances may be present as impurities, but their levels are expected to be below 100 ppm.
23	Conflict Minerals	Y				Not been intentionally added as ingredients in the manufacture of the above mentioned product(s) and, to the best of our knowledge, are not known to be present in the final product(s).

24	Consumer Product Safety Improvement Act of 2008 (CPSIA)				See Comment	Our Supplier has not indicated if this material meets these standards.
25	Drug Master File	Y				To the best of our knowledge this material is not Listed.
26	Endotoxins				See Comment	Not used in the manufacture or formulation of this product.
27	EU 200/53/EC & 2002/525/EC -END-OF-Life Vehicles Regulation				See Comment	Our Supplier has not indicated if this material meets these standards.
28	EU Commission Decision 2009/251/EC – Dimethyl fumarate	Y				This product does not contain the biocide Dimethyl fumarate.
29	EU Directive 2002/16/EC				See Comment	Our Supplier has not indicated if this material meets these standards.
30	EU Directive 2003/11/EC				See Comment	Our Supplier has not indicated if this material meets these standards.
31	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromocyclododecane (HBCDD) and Hexachlorobenzene (HCB)				See Comment	Our Supplier has not indicated if this material meets these standards.
32	EU Directive 90/128 and subsequent amendments				See Comment	Our Supplier has not indicated if this material meets these standards.
33	EU MDR	Y				Concerning regulation (EU) 2017/745 regarding materials used in medical devices; in reference to Annex I, Chapter II, Part 10.4 (substances), the supplier confirms this resin does not contain the following substances at concentrations above 0.1 weight % based on the formulation, manufacturing process and information from the raw material suppliers: - CMR Category 1A or 1B in accordance with Part 3 of Annex VI of Regulation (EC) No 1272/2008. Endocrine-disrupting substances 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 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.

34	EU-Food Contact (EC) No 1935/2004				See Comment	Our Supplier has not indicated if this material meets these standards.
35	EU-Pharmacopeia (7th Edition)				See Comment	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				See Comment	Our Supplier has not indicated if this material meets these standards.
37	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)				See Comment	Our Supplier has not indicated if this material meets these standards.
38	Formaldehyde	Y				Not used in the manufacture or formulation of this product.
39	Genetically Modified Organism Free	Y				Not used in the manufacture or formulation of this product.
40	GHS	Y				Not used in the manufacture or formulation of this product.
41	Gluten-Free	Y				Not used in the manufacture or formulation of this product.
42	ILFI – Red List Chemicals The International Living Future Institute	Y				Not used in the manufacture or formulation of this product.
43	In Vitro Hemocompatibility Assay (ISO)				See Comment	Our Supplier has not indicated if this material meets these standards.
44	International Inventories				See Comment	listed or not restricted.
45	ISO 10993-1				See Comment	Our Supplier has not indicated if this material meets these standards.
46	ISO 10993-10				See Comment	Our Supplier has not indicated if this material meets these standards.
47	ISO 10993-11				See Comment	Our Supplier has not indicated if this material meets these standards.
48	ISO 10993-12				See Comment	Our Supplier has not indicated if this material meets these standards.
49	ISO 10993-18, EXTRACTABLES TESTING				See Comment	Our Supplier has not indicated if this material meets these standards.
50	ISO 10993-2				See Comment	Our Supplier has not indicated if this material meets these standards.
51	ISO 10993-3				See Comment	Our Supplier has not indicated if this material meets these standards.
52	ISO 10993-4				See Comment	Our Supplier has not indicated if this material meets these standards.
53	ISO 10993-5				See Comment	Our Supplier has not indicated if this material meets these standards.

54	ISO 10993-6				See Comment	Our Supplier has not indicated if this material meets these standards.
55	Kosher		N			Supplier does not certify this resin to be Kosher or in compliance with Kosher Requirements.
56	Lactose	Y				Not used in the manufacture or formulation of this product.
57	Latex	Y				Not used in the manufacture or formulation of this product.
58	MA Right to Know Extraordinarily Hazardous Substance List				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
59	Melamine	Y				Not used in the manufacture or formulation of this product.
60	Natural Rubber	Y				Not used in the manufacture or formulation of this product.
61	Nitrosamines	Y				Not used in the manufacture or formulation of this product.
62	NJ Right to Know Regulated Chemicals				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
63	Nanoparticles	Y				Not used in the manufacture or formulation of this product.
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.

					The following substances are not used as additives or ingredients in the manufacture of the above mentioned product: 1,3-Dihydroxybenzene (Resorcinol, CAS No. 108-46-3); 1,3-Di-o-tolylguanidine (DOTG, CAS No. 97-39-2); 2-Isopropylthioxanthone (ITX, CAS No. 5495-84-1); Antimony (CAS No. 7440-36-0); Antimony trioxide (CAS No. 1309-64-4); Arsenic, Beryllium, Cadmium, Chromium (VI), Lead, Mercury, Selenium and their compounds; Asbestos; Azodyes which, by reductive cleavage of one or more azo groups, may release any of a group of aromatic amines defined in Directive 2002/61/EC; Benzenamine, N-phenylreaction products with styrene and 2,4,4-trimethylpentene (BNST, CAS No. 68921-45-9); Benzophenone (CAS No. 119-61-9); 1H-1,2,3-Benzotriazol (CAS No. 95-14-7); Bisphenol B (4,4'-(1-methylpropylidene)bisphenol, CAS No. 77-40-7); Bisphenol F (4,4'-methylenediphenol, CAS No. 620-92-8); Bisphenol S (4,4'-sulphonyldiphenol, CAS No. 80-09-1); Butylated hydroxyanisole (BHA, CAS No. 25013-16-5, 121-00-6); Camphor (CAS No. 76-22-2, 464-49-3, 464-48-2); Chlorinated naphthalenes; Chlorinated paraffins; Cobalt (CAS No. 7440-48-4); Creosote (CAS No. 8001-58-9); Diisooctyl phthalate (CAS No. 27554-26-3); Dimethylfumarate (DMF, CAS No. 624-49-7); DIOP (O-Isopropylidene-2,3-dihydroxy-1,4-bis(diphenylphosphino)butane, CAS No. 32305-98-9; 37002-48-5); Lindane (CAS No. 58-89-9); Mercapto-2-benzothiazole (2-MBT, CAS No. 149-30-4); Mica (CAS No. 12001-26-2); Nickel (CAS No. 7440-02-0); Nonylphenol and nonylphenol ethoxylates; Octylphenol and octylphenol ethoxylates; Organotin compounds; Parabene; Pentachlorophenol (CAS No. 87-86-5); Phthalates; Polybrominated biphenyls (PBBs); Polybrominated diphenylethers (PBDEs), including:Decabromodiphenylether (Deca-BDE), Octabromodiphenylether (Octa-BDE), Pentabromodiphenylether (Penta-BDE); Polychlorinated biphenyls; Polychlorinated dibenzo-p-dioxins; Polychlorinated
	Other Substance/compounds	Y			

67					dibenzofurans; Polychlorinated terphenyls (PCTs, CAS No. 61788-33-8); Polycyclic Aromatic Hydrocarbons (PAHs), but for colored materials the carbon black used for the coloration of the product may contain PAHs; Polyvinylchloride (CAS No. 9002-86-2); Polyvinylidenchloride (PVDC, CAS No. 9002-85-1); Red Phosphorus (CAS No. 7723-14-0); Short Chain Chlorinated Paraffins (CAS No. 85535-84-8); Sulfur hexafluoride (SF6, CAS No. 2551-62-4); Tetrabromobisphenol A (CAS No. 79-94-7); Triclosan (2,4,4'-Trichloro-2'-hydroxy-diphenyl-ether, CAS No. 3380-34-5); Tris(1,3-dichloro-2-propyl) phosphate (TDCPP, CAS No. 13674-87-8); Tris(1-aziridinyl)phosphine oxide (CAS No. 545-55-1); Tris(2,3-dibromopropyl) phosphate (TBPP, CAS No. 126-72-7); Tris(2-chloro-1-methylethyl) phosphate (TCPP, CAS No. 237-158-7, 13674-84-5); Tris(2-chloroethyl) phosphate (TCEP, CAS No. 115-96-8); Vinylchloride (CAS No. 75-01-4)
68	Ozone Depleting Substances	Y			Not used in the manufacture or formulation of this product.
69	PA Right to Know Regulated Chemicals			See Comment	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 supplier of this raw material confirms the substances listed in Annex 1 of Regulation (EU) 2019/1021, 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	PFAS (Per and Polyfluoroalkyl substances)	Y			Not used in the manufacture or formulation of this product.
72	PFCA (Perfluoroalkyl carboxylic acid)	Y			Not used in the manufacture or formulation of this product.
73	PFOA (Perfluorooctanoic acid)	Y			Not used in the manufacture or formulation of this product.

74	PFOS (Perfluorooctanoic sulfonate)	Y				Not used in the manufacture or formulation of this product.
75	Phthalates: Dibutyl phthalate Diethyl 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	Y				Not used in the manufacture or formulation of this product.
76	REACH	Y				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 February 4, 2026 (cumulative), or chemical substances restricted for specific applications listed in Annex XVII or chemicals listed in the substance of very high concern identification list are neither used as raw materials nor as auxiliary materials in the manufacturing process of this product.

77	RoHS / RoHS 2 / RoHS 3	Y				This material 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. Any trace amounts of these substances would not be expected to be above the regulated thresholds.
78	SARA (311,312) Hazard Class				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
79	SARA 313 Regulated Chemicals				See Comment	Styrene: 0.1%/Threshold standard Acrylonitrile: 0.1%/Threshold standard 1,3-Butadiene:0.1%/Threshold standard Methyl methacrylate: Conc. 1.0% / Threshold Standard
80	SARA Title III – Section 302 Extremely Hazardous Chemicals:				See Comment	Acrylonitrile's: TPQ 10000 lbs. / RQ 100 lbs.
81	Transport Classification	Y				Not regulated as hazardous for shipment.
82	TSCA	Y				This material is not intentionally formulated with any of the following compounds: • Decabromodiphenyl ether (DecaBDE) • Phenol, isopropylated phosphate (3:1) (PIP (3:1)) • 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) • Hexachlorobutadiene (HCBD) • Pentachlorothiophenol (PCTP)
83	Unactivated Partial Thromboplastin Time Assay (ISO)				See Comment	Our Supplier has not indicated if this material meets these standards.
84	US Pharmacopeia Class VI				See Comment	Our Supplier has not indicated if this material meets these standards.
85	USDA				See Comment	Our Supplier has not indicated if this material meets these standards.
86	USP 85 (Endotoxin)				See Comment	Our Supplier has not indicated if this material meets these standards.
87	USP 87 (L929 MEM Elution)				See Comment	Our Supplier has not indicated if this material meets these standards.
88	USP 88				See Comment	Our Supplier has not indicated if this material meets these standards.
89	USP 381 (Elastomeric Closures for injection)				See Comment	Our Supplier has not indicated if this material meets these standards.

90	USP 643 (Total Organic Carbon)				See Comment	Our Supplier has not indicated if this material meets these standards.
91	USP 661				See Comment	Our Supplier has not indicated if this material meets these standards.
92	USP 665 (Single - use systems (SUS) & the risk associated with extractable & leachables (E&L)				See Comment	Our Supplier has not indicated if this material meets these standards.
93	USP 851 (Static Sorption Study of Phenol)				See Comment	Our Supplier has not indicated if this material meets these standards.
94	Volatile Organic Compounds (VOCs)				See Comment	Not used in the manufacture or formulation of this product.
95	WEEE	Y				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.

