



CERTIFICATE OF COMPLIANCE

DATE: October 17, 2025

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.

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.

			(СОМР	LIANT	COMMENTS
						Comments below are mostly summaries
						of supplier compliance statements.
					See	Detailed supplier's statements available
ITEM	REGULATORY REQUIREMENTS	Υ	Ν	N/A	Comment	upon request.
						Not intentionally added in the
	Allergens (Global Food)	Υ				manufacturing of or formulation. Due to
	Alleigelis (Global Food)	'				the absence of use of these substances,
1						we do not test for them.
						The supplier of this material has
						not indicated if this product was
	Corn / Plant / Vegetable	Υ				manufactured using raw material
2						or of corn/plant/vegetable origin.
						Not intentionally added in the
	ELV Directive 2000/53/EC	Ιγ				manufacturing of or formulation. Due to
	(Heavy Metal)	'				the absence of use of these substances,
3						we do not test for them.
	21 CFR 177.2510, 177.2600,					
	177.1520, 21 CFR 178.3297,					
	21 CFR 176.170, 21 CFR					
	177.1500, 21 CFR 177.1580,				See	
	21 CFR 177.1520(a)(3)(a) and				Comment	Our Supplier has not indicated if this
	(c) 3.1a, 21 CFR 177.1550, 21					material meets these standards.
	CFR 177.2470, 21 CFR					
	177.2480, 21 CFR 177.2600,					
	21 CFR 177.2600					
4	(Food Contact)					
	3-A Sanitary Standards				See	Our Supplier has not indicated if this
5	•				Comment	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	Υ		The facility manufacturing these products not required to register with the Bioterrorism.
14	BISPHENOL A (BPA)	Υ		Act of 2002 because it is not a food facility.

15	BSE/TSE	Y	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 laid down in the note for guidance EMEA/410/01 Rev. 02 (October 2009) adopted by the CPMP (Committee for Proprietary Medicinal Products) and CVMP (Committee for Veterinary Medicinal Products). In addition, the treatment exceeds the requirements of the directive 2000/6/EG Annex II. These specified conditions are sufficient to inactivate TSE transmitter. Accordingly, transmission of animal spongiform encephalopathy agents via the mentioned plastics is extremely improbable.
16	California Prop 65	Y	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 our Terlux® 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 DISCLOUSRE 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 SOCMI 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
20	Comprehensive Environmental Response,			See	Styrene: CERCLA: RQ 1000 lbs. Acrylonitrile: CERCLA: RQ 100 lbs 1,3-
	Compensation, and Liability Act (CERCLA) - Reportable			Comment	Butadiene: CERCLA: RQ 10 lbs Methyl methacrylate: Hazardous Substances: RQ
21	Quantity (RQ):				1000 lbs.
	CONEG	Υ			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
22					expected to be below 100 ppm.

23	Conflict Minerals	Υ		Not used in the manufacture or formulation of this product.
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	Υ		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	Υ		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.

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33	EU MDR	Υ		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	Υ		Not used in the manufacture or formulation of this product.
39	Genetically Modified Organism Free	Υ		Not used in the manufacture or formulation of this product.
40	GHS	Υ		Not used in the manufacture or formulation of this product.
41	Gluten-Free	Υ		Not used in the manufacture or formulation of this product.
42	ILFI – Red List Chemicals The International Living Future Institute	Υ		Not used in the manufacture or formulation of this product.

	In Vitua Harranana - Atlatte	I			Our Cumplion has not indicated if this
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	Υ			Not used in the manufacture or formulation of this product.
57	Latex	Υ			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	Υ			Not used in the manufacture or formulation of this product.
60	Natural Rubber	Υ			Not used in the manufacture or formulation of this product.
61	Nitrosamines	Υ			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	Υ			Not used in the manufacture or formulation of this product.

		Т		_
	NSF 61		See	See
64	1.01.02		Comment	https://www.nsf.org/certified-
				products-systems for reference.
	NCE 44		See	See
65	NSF-14		Comment	https://www.nsf.org/certified-
				products-systems for reference.
		T	See	See
66	NSF-51		Comment	
66			Comment	https://www.nsf.org/certified-
		+		products-systems for reference.
				The following are not used in Manufacture
				or formulation of this product:
				Vinylchloride, Triclosan, Polyfluoroalkyl
				substances (PFAS), Polychlorinated dibenzo-
				p-dioxins / Polychlorinated dibenzofurans,
				Polychlorinated biphenyls,
				Perflourooctanoic acid – Perflourooctane
				sulfate (PFOA / PFOS), - Group I to VII (Class
				I USA) Group I Chlorofluorocarbons
				-Group II other fully halogenated
				Chloroflourocarbons
	Other Substance/compounds	Y		- Group III Halons
				- Group IV Carbontetrachloride
				- Group V 1,1,1 – Trichloroethane
				- Group VII Hydrobromofluorocarbons
				- Group VIII (Class II USA)
				hydroflourocarbons
				-Group IX Bromochloromethane, Organotin
				compounds, Nonylphenol – nonylphenol
				ethoxylates, Melamine, LATEX,
				Hexabomocyclododecane, Formaldehyde,
				Dimethylfumarate, cassiterite, columbite-
				tantalite, gold, wolframite, and their
				derivatives, Chlorinated
				paraffins, Chlorinated naphthalenes,
67				Bisphenol A / Bisphenol S,
07				Asbestos, Arsenic
		١.,		Not used in the manufacture or
68	Ozone Depleting Substances	Y		formulation of this product.
		T	See	To the best of our knowledge, this product
	PA Right to Know Regulated		Comment	does not contain chemicals at levels which
	Chemicals			require reporting under this statute.
69	Chemicals			. equite reporting under this statute.
		1	+	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
	Persistent Organic Pollutants	Υ		not intentionally added during the
	(POP)			not intentionally added during the
	· · · · · ·	-	 	

PFAS (Per and Polyfluoroalkyl substances) PFCA 72 (Perfluoroalkyl carboxylic acid) PFOA (Perfluorooctanoic acid) PFOS (Perfluorooctanoic sulfonate) 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	evaluate for them.
PFOA (Perfluorooctanoic acid) PFOS (Perfluorooctanoic sulfonate) 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	Not used in the manufacture or formulation of this product.
PFOS (Perfluorooctanoic sulfonate) 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	Not used in the manufacture or formulation of this product.
Phthalates: Dibutyl phthalate Dioctyl phthalate (DEHP) Di-isononyl phthalate DIMP 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	Not used in the manufacture or formulation of this product.
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	Not used in the manufacture or formulation of this product.
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	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 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.
77	RoHS / RoHS 2 / RoHS 3	Υ		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	Υ		Not regulated as hazardous for shipment.
82	TSCA	Υ		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.

			See	Our Supplier has not indicated if this
84	US Pharmacopeia Class VI		Commen	
	USDA		See	Our Supplier has not indicated if this
85	USDA		Comment	material meets these standards.
	USP 85		See	Our Supplier has not indicated if this
86	(Endotoxin)		Comment	material meets these standards.
	USP 87		See	Our Supplier has not indicated if this
87	(L929 MEM Elution)		Comment	material meets these standards.
	USP 88		See	Our Supplier has not indicated if this
88			Commen	
	USP 381		See	Our Supplier has not indicated if this
89	(Elastomeric Closures for injection)		Comment	material meets these standards.
	USP 643		See	Our Supplier has not indicated if this
90	(Total Organic Carbon)		Comment	
30	,		Comment	
	USP 661		See	Our Supplier has not indicated if this
91			Comment	material meets these standards.
	USP 665		See	
	(Single - use systems (SUS) &		Comment	Our Supplier has not indicated if this
	the risk associated with			material meets these standards.
92	extractable & leachables (E&L)			
	USP 851		See	Our Supplier has not indicated if this
	(Static Sorption Study of Phenol)		Comment	material meets these standards.
93	Filelioij			
	Volatile Organic Compounds		See	Not used in the manufacture or
94	(VOCs)		Comment	formulation of this product.
				The WEEE-Directive regulates disposal and
				recycling of electrical and electronic
	WEEE	Υ		waste. Compliance with the restrictions of
				this directive can only be confirmed by the
95				producer of the final product. To our best
				knowledge this product is compliant.