

## CERTIFICATE OF COMPLIANCE

**DATE:** April 16, 2024  
**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:** STRYOLUTION <http://www.styrolution.com/INTERSHOP/web/WFS/Styrolution-Portal-Site>

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://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Material-Information/> and <https://www.nordsonmedical.com/Resources/Regulatory-Compliance> . 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**

Manufacturing and Quality Manager

**Nordson Medical**

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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	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.
3	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
4	3-A Sanitary Standards				See Comment	Our Supplier has not indicated if this material meets these standards

5	<b>AD-DSL (the AeroSpace &amp; Defence 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.
6	<b>Animal Derived Materials</b>				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
7	<b>Aromatic Amines</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.
8	<b>ASTM D3222</b>				See Comment	Our Supplier has not indicated if this material meets these standards
9	<b>ASTM F963 Standard Consumer Safety for Toy Safety</b>				See Comment	Our Supplier has not indicated if this material meets these standards
10	<b>BioCides</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.
11	<b>Biocompatibility</b>				See Comment	Our Supplier has not indicated if this material meets these standards
12	<b>Bioterrorism Act of 2002</b>	Y				The facility manufacturing these products not required to register with the Bioterrorism
13	<b>BISPHENOL A (BPA)</b>	Y				Act of 2002 because it is not a food facility.

14	BSE/TSE	Y			<p>Our Supplier has indicated that the primary components of this resin are petrochemical in nature, not from cattle, sheep, or goat.</p> <p>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.</p>
15	California Prop 65	Y			<p>Please be advised that the above grade contains 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 in question are:</p> <ul style="list-style-type: none"> <li>- acrylonitrile (CAS No. 107-13-1) &lt; 30 ppm</li> <li>- 1,3-butadiene (CAS No. 106-99-0) &lt; 1 ppm</li> <li>- ethylbenzene (CAS No. 100-41-4) &lt; 20 ppm</li> <li>- 4-vinylcyclohexene (CAS No. 100-40-3) &lt; 20 ppm</li> <li>- styrene (CAS No. 100-42-5) &lt; 1000 ppm</li> </ul> <p>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) (CAS No. 98-82-8). Though this is not routinely measured for, and the levels are</p>

					<p>expected to be very low. Additionally, the resin manufacturer has no information to suggest that exposure to the low levels of above-mentioned substances found in the Terlux resins poses any significant risk to the end-user or consumer.</p> <p>Finally, to the best of our knowledge, this product does not contain above mentioned substances in concentrations above 0.01 %. However, the observance of all these substances is not part of our ongoing production control. As many factors may affect processing and applications of this product, the customer must make their own determination that this material is safe and suited for its intended application.</p>
16	<b>Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS</b>	Y			<p>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.</p>
17	<b>Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington</b>			See Comment	<p>To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.</p>
18	<b>China RoHS</b>			See Comment	<p>Our Supplier has not indicated if this material meets these standards</p>

19	Clean Air Act, 40 CFR				See Comment	<p>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</p>
20	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):				See Comment	<p>Styrene: CERCLA: RQ 1000 lbs. Acrylonitrile: CERCLA: RQ 100 lbs 1,3- Butadiene: CERCLA: RQ 10 lbs Methyl methacrylate: Hazardous Substances: RQ 1000 lbs.</p>
21	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.
22	Conflict Minerals	Y				Not used in the manufacture or formulation of this product.
23	Consumer Product Safety Improvement Act of 2008 (CPSIA)				See Comment	Our Supplier has not indicated if this material meets these standards
24	Drug Master File	Y				To the best of our knowledge this Material is not Listed.
25	Endotoxins				See Comment	Not used in the manufacture or formulation of this product.
26	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

27	<b>EU Commission Decision 2009/251/EC – Dimethylfumarate</b>	Y				This product does not contain the biocide Dimethylfumarate.
28	<b>EU Directive 2002/16/EC</b>				See Comment	Our Supplier has not indicated if this material meets these standards
29	<b>EU Directive 2003/11/EC</b>				See Comment	Our Supplier has not indicated if this material meets these standards
30	<b>EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenze (HCB) –</b>				See Comment	Our Supplier has not indicated if this material meets these standards
31	<b>EU Directive 90/128 and subsequent ammendments</b>				See Comment	Our Supplier has not indicated if this material meets these standards
32	<b>EU MDR</b>	Y				<p>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:</p> <ul style="list-style-type: none"> <li>- CMR Category 1A or 1B in accordance with Part 3 of Annex VI of Regulation (EC) No 1272/2008.</li> <li>- 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.</li> <li>- Phthalates</li> </ul>
33	<b>EU-Food Contact</b>				See Comment	Our Supplier has not indicated if this material meets these standards

34	<b>EU-Pharmacopeia (7th Edition)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
35	<b>European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste</b>				See Comment	Our Supplier has not indicated if this material meets these standards
36	<b>European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
37	<b>Formaldehyde</b>	Y				Not used in the manufacture or formulation of this product.
38	<b>Genetically Modified Organism Free</b>	Y				Not used in the manufacture or formulation of this product.
39	<b>GHS</b>	Y				Not used in the manufacture or formulation of this product.
40	<b>Gluten-Free</b>	Y				Not used in the manufacture or formulation of this product.
41	<b>ILFI – Red List Chemicals The International Living Future Institute</b>	Y				Not used in the manufacture or formulation of this product.
42	<b>In Vitro Hemocompatibility Assay (ISO)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
43	<b>International Inventories</b>				See Comment	listed or not restricted
44	<b>ISO 10993-1</b>				See Comment	Our Supplier has not indicated if this material meets these standards
45	<b>ISO 10993-10</b>				See Comment	Our Supplier has not indicated if this material meets these standards
46	<b>ISO 10993-11</b>				See Comment	Our Supplier has not indicated if this material meets these standards
47	<b>ISO 10993-12</b>				See Comment	Our Supplier has not indicated if this material meets these standards
48	<b>ISO 10993-18, EXTRACTABLES TESTING</b>				See Comment	Our Supplier has not indicated if this material meets these standards
49	<b>ISO 10993-2</b>				See Comment	Our Supplier has not indicated if this material meets these standards
50	<b>ISO 10993-3</b>				See Comment	Our Supplier has not indicated if this material meets these standards



51	<b>ISO 10993-4</b>				See Comment	Our Supplier has not indicated if this material meets these standards
52	<b>ISO 10993-5</b>				See Comment	Our Supplier has not indicated if this material meets these standards
53	<b>ISO 10993-6</b>				See Comment	Our Supplier has not indicated if this material meets these standards
54	<b>Kosher</b>		N			Supplier does not certify this resin to be Kosher or in compliance with Kosher requirements
55	<b>Lactose</b>	Y				Not used in the manufacture or formulation of this product.
56	<b>Latex</b>	Y				Not used in the manufacture or formulation of this product.
57	<b>MA Right to Know Extraordinarily Hazardous Substance List</b>				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
58	<b>Melamine</b>	Y				Not used in the manufacture or formulation of this product.
59	<b>Natural Rubber</b>	Y				Not used in the manufacture or formulation of this product.
60	<b>Nitrosamines</b>	Y				Not used in the manufacture or formulation of this product.
61	<b>NJ Right to Know Regulated Chemicals</b>				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
62	<b>Nanoparticles</b>	Y				Not used in the manufacture or formulation of this product.
63	<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.
64	<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.
65	<b>NSF-51</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.

66	Other Substance/compounds	Y				<p>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, Perfluorooctanoic acid – Perfluorooctane sulfate (PFOA / PFOS), - Group I to VII (Class I USA)</p> <ul style="list-style-type: none"> <li>- Group I Chlorofluorocarbons</li> <li>-Group II other fully halogenated Chlorofluorocarbons</li> <li>- Group III Halons</li> <li>- Group IV Carbontetrachloride</li> <li>-Group V 1,1,1 – Trichloroethane</li> <li>- Group VII Hydrobromofluorocarbons</li> </ul> <p>- Group VIII (Class II USA) hydrofluorocarbons</p> <p>-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, Bisphenol A / Bisphenol S, Asbestos, Arsenic</p>
67	Ozone Depleting Substances	Y				Not used in the manufacture or formulation of this product.
68	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.
69	Persistent Organic Pollutants (POP)	Y				Not used in the manufacture or formulation of this product.
70	PFAS (Per and Polyfluoroalkyl substances)	Y				Not used in the manufacture or formulation of this product.
71	PFCA (Perfluoroalkyl carboxylic acid)	Y				Not used in the manufacture or formulation of this product.
72	PFOA (Perfluorooctanoic acid)	Y				Not used in the manufacture or formulation of this product.
73	PFOS (Perfluorooctane sulfonate)	Y				Not used in the manufacture or formulation of this product.

74	<b>Phthalates:</b> <b>Dibutyl phthalate</b> <b>Diethyl phthalate (DEHP)</b> <b>Di-isononyl phthalate</b> <b>Dimethyl phthalate</b> <b>DMP CAS# 131-11-3</b> <b>Diethyl phthalate DEP CAS# 84-66-2</b> <b>Diallyl phthalate DAP CAS# 131-17-9</b> <b>Di-n-propyl phthalate DPP CAS# 131-16-8</b> <b>Di-n-butyl phthalate DBP CAS# 84-74-2</b> <b>Diisobutyl phthalate DIBP CAS# 84-69-5</b> <b>Butyl cyclohexyl phthalate BCP CAS# 84-64-0</b> <b>1,2-bis(2-methoxyethyl) ester DMEP CAS# 117-82-8 [bis(2-methoxyethyl) phthalate]</b> <b>Di-n-pentyl phthalate DNPP CAS# 131-18-0</b> <b>1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3</b> <b>Dicyclohexyl phthalate DCP CAS# 84-61-7</b> <b>Butyl benzyl phthalate BBP CAS# 85-68-7</b> <b>Di-n-hexyl phthalate DnHP CAS# 84-75-3</b>	Y				Not used in the manufacture or formulation of this product.
75	<b>REACH</b>	Y				Our supplier has indicated that this product does not contain any of the substances of very high concern above a concentration of 0.1%.
76	<b>RoHS / RoHS 2 / RoHS 3</b>	Y				This material conforms to the substance limits and prohibition requirements of RoHS 2, directive 2011/65/EU, as amended by 2015/863/EU.

77	<b>SARA (311,312) Hazard Class</b>				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
78	<b>SARA 313 Regulated Chemicals</b>				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
79	<b>SARA Title III – Section 302 Extremely Hazardous Chemicals:</b>				See Comment	Acrylonitrile's: TPQ 10000 lbs. / RQ 100 lbs.
80	<b>Transport Classification</b>	Y				Not regulated as hazardous for shipment.
81	<b>TSCA</b>	Y				This material is not intentionally formulated with any of the following compounds: <ul style="list-style-type: none"> <li>• Decabromodiphenyl ether (DecaBDE)</li> <li>• Phenol, isopropylated phosphate (3:1) (PIP (3:1))</li> <li>• 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) <ul style="list-style-type: none"> <li>• Hexachlorobutadiene (HCBD)</li> <li>• Pentachlorothiophenol (PCTP)</li> </ul> </li> </ul>
82	<b>Unactivated Partial Thromboplastin Time Assay (ISO)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
83	<b>US Pharmacopoeia Class VI</b>				See Comment	Our Supplier has not indicated if this material meets these standards
84	<b>USDA</b>				See Comment	Our Supplier has not indicated if this material meets these standards
85	<b>USP 381 (Elastomeric Closures for injection)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
86	<b>USP 643 (Total Organic Carbon)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
87	<b>USP 661</b>				See Comment	Our Supplier has not indicated if this material meets these standards
88	<b>USP 85 (Endotoxin)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
89	<b>USP 88</b>				See Comment	Our Supplier has not indicated if this material meets these standards

90	<b>USP 851 (Static Sorption Study of Phenol)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
91	<b>USP 87 (L929 MEM Elution)</b>				See Comment	Our Supplier has not indicated if this material meets these standards
92	<b>Volatile Organic Compounds (VOCs)</b>				See Comment	Not used in the manufacture or formulation of this product.
93	<b>WEEE</b>	Y				No deliberately added brominated flame retardants.

