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CERTIFICATE OF COMPLIANCE

DATE: June 2, 2025
SUBJECT: **REGULATORY COMPLIANCE FOR VALUE PLASTCS PRODUCTS** ALL
PART AFFECTED: VALUE PLASTICS PRODUCTS WITH SUFFIX OF -9010 MAKROLON
MATERIAL TYPE: RX1805 RAD STABLE POLYCARBONATE RESIN
SUPPLIER: Covestro http://www.plastics.covestro.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://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.

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

Nordson Medical
Email: LOV_QA-RA@nordsonmedical.com

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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	Comments below are mostly summaries of supplier compliance statements. Detailed supplier's statements available upon request.
1	**Allergens (Global Food)**				See Comment	Various plant sources may have been used, including palm, soybean, and rapeseed oils. Nevertheless, since the derivation processes destroys cellular structures, the non-viable chemical substances used are not expected to contain GMO's, natural rubber latex, Jatropha, Colophony, or plant allergens.
2	**Corn / Plant / Vegetable**	Y				The supplier of this material has indicated this product may have been manufactured using raw material or of plant 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.
	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

4						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**	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	**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 this product is not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
14	**BISPHENOL A (BPA)**				See Comment	Residual BPA in polycarbonate resin is generally less than 50 ppm. The BPA level in resin may vary according to design and processing conditions. To determine BPA levels, you will need to test your product.
15	**BSE/TSE**	Y				This resin is a synthetic petrochemical product which does not contain materials that are derived from animal sources.
16	**California Prop 65**				See comment	This product contains chemical(s) known to the State of California to be carcinogenic: Methylene Chloride (3 ppm). CAS-No. 75-09-2. Bisphenol A (Trace element) CAS-No. 80-05-7.
17	**Canadian WHMIS INGREDIENT DISCLOUSRE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS**	Y				All substances contained in this product are listed on the Canadian Domestic Substances List (DSL) or are not required to be listed. This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document, with the exception of Bisphenol A (BPA) (CAS# 80-05-7) listed under Batch 2 Challenge Substances. Please be advised that we do not analyze for these specific substances.
18	**Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington**				See Comment	Bisphenol A poly carbonate (1%) CAS-No. 25971-63-5.

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, 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 below.
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 - Hexabromocyclododecane (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**	Y				To the best of our knowledge, Covestro product MAKROLON Rx1805 451118 complies with the material requirements of 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. Also, to the best of our knowledge, this product complies with Commission Regulation 722/2012 regarding medical devices manufactured utilizing tissues of animal origin.
34	**EU-Food Contact**				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		The European Pharmacopeia does not contain polycarbonate specific requirements.
36	**European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste**			N/A		Our Supplier has not indicated if this material meets these standards.
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				Not intentionally added during manufacture or formulation of this product.
40	**GHS**	Y				This product is not hazardous in the form in which it is shipped by the manufacturer. GHS Signal word: Warning GHS Hazard Statements: If fine particles are generated during further processing, handling, or by other means, product may form combustible dust concentrations in air.
41	**Gluten-Free**				See Comment	This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
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 be tested against these standards to our knowledge.
44	**International Inventories**	Y				A "Listed" entry above means all chemical components are on the respective inventory list and/or a qualifying exemption exists for one or more components. A "Not listed" entry above indicates one or more components is restricted from import or manufacture into that country/region. Articles are exempt from registration and are therefore not listed on the national chemical inventories. TSCA (USA): Listed DSL (Canada): Listed EINECS/ELINCS (Europe): Listed ENCS (Japan): Listed IECSC (China): Listed KECL (Korea): Listed PICCS (Philippines): Listed AICS (Australia): Listed

45	**ISO 10993-1**	Y				Makrolon Rx1805 resin is designated as “medical grade” and has met the requirements of the FDA-Modified ISO 10993, Part 1 “Biological Evaluation of Medical Devices” tests with human tissue contact time of 30 days or less.
46	**ISO 10993-10**			N/A		This material has not been tested against these standards to our knowledge.
47	**ISO 10993-11**			N/A		This material has not been tested against these standards to our knowledge.
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**			N/A		This material has not been tested against these standards to our knowledge.
53	**ISO 10993-5**			N/A		This material has not been tested against these standards to our knowledge.
54	**ISO 10993-6**			N/A		This material has not been tested against these standards to our knowledge.
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 used in the manufacture or formulation of this product.
58	**MA Right to Know Extraordinarily Hazardous Substance List**				See Comment	Methylene Chloride (3 ppm). CAS-No. 75-09-2 Bisphenol A poly carbonate (1%) CAS-No. 25971-63-5.

59	**Melamine**	Y				Not intentionally 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				Nitrosamines may in theory be formed from secondary or tertiary amines. For our polycarbonate products this is highly improbable, since the conditions during plastics manufacture and storage do not favor nitration. Specifically, nitrous acid and nitrous salts are not used in the manufacturing process, the pH of the aqueous phase during manufacturing is unfavorable, and the potential residual secondary/tertiary amine concentration is well below 1 ppm in the product.
62	**NJ Right to Know Regulated Chemicals**				See Comment	Bisphenol A poly carbonate (1%) CAS-No. 25971-63-5.
63	**Nanoparticles**	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
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 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,

67	**Other Substance / Compounds**				See Comment	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, 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-dioxins/ 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.

68	**Ozone Depleting Substances**	Y				Not used in the manufacture or formulation of this product.
69	**PA Right to Know Regulated Chemicals**				See Comment	Bisphenol A poly carbonate (1%) CAS-No. 25971-63-5.
70	**Persistent Organic Pollutants (POP)**	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.
71	**PFAS (Per and Polyfluoroalkyl substances)**	Y				Not intentionally added during the manufacture or formulation of this product.
72	**PFCA (Perfluoroalkyl carboxylic acid)**	Y				Not intentionally added during the manufacture or formulation of this product.
73	**PFOA (perfluorooctanoic acid)**	Y				Not intentionally added during the manufacture or formulation of this product.
74	**PFOS (Perfluorooctanoate sulfonate)**	Y				Not intentionally added during the manufacture or formulation of this product.

75	**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**	Y				Not intentionally added during the manufacture or formulation of this product.
	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 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

76						used as raw materials nor as auxiliary materials in the manufacturing process of this product.
77	**RoHS / RoHS 2 / RoHS 3**	Y				This product 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. Product has not been analyzed for these substances or compounds; any trace amounts of these substances would not be expected to be above the regulated thresholds.
78	**SARA (311,312) Hazard Class**	Y				Non-hazardous under Section 311/312.
79	**SARA 313 Regulated Chemicals**	Y				AS far as our knowledge this product is Not listed/Not regulated.
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				Listed on the Active Portion of the TSCA Inventory. No substances are subject to TSCA 12(b) export notification requirements.
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				This material has been tested and has met the biocompatibility and physiochemical testing requirements according to USP Plastics Class VI.
85	**USDA**				N/A	This material has not been tested against these standards to our knowledge.
86	**USP 381 (Elastomeric Closures for injection)**				N/A	This material has not been tested against these standards to our knowledge.
87	**USP 643 (Total Organic Carbon)**				N/A	This material has not been tested against these standards to our knowledge.

88	**USP 661**				N/A	This material has not been tested against these standards to our knowledge.
89	**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.
90	**USP 85 (Endotoxin)**					This material has not been tested against these standards to our knowledge.
91	**USP 851 (Static Sorption Study of Phenol)**				N/A	This material has not been tested against these standards to our knowledge.
92	**USP 87 (L929 MEM Elution)**					This material has not been tested against these standards to our knowledge.
93	**USP 88**				N/A	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 2012/19/EU 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. However, to the best of our knowledge, for the above-mentioned products the supplier confirms that they do not contain any substances listed in Annex II of this directive (2002/96/EC) as an intentional ingredient.