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CERTIFICATE OF COMPLIANCE

DATE: March 30, 2026
SUBJECT: **REGULATORY COMPLIANCE FOR VALUE PLASTCS PRODUCTS**
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -CM056
MATERIAL TYPE: SOLMED GRANUFLEX 4301 NATURAL POLYETHYLENE
SUPPLIER: Renolit http://www.renolit.com/medical/en/

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 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 leters 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.

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)**	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 corn/plant/vegetable 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					All raw materials as used for this supplier's polyethylene based biotechnology plastics for single use purposes (including granuflex) conform to at least one of the following (sub-)Sections of 21 CFR 177 and related Sections: 175.105 – Adhesives (indirect food additives) 176.170 – Components of paper

4	**(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)**					and paperboard in contact with aqueous and fatty foods 177.1360 – Ethylene-vinyl alcohol copolymers 177.1395 – Polymers: Laminate structures for use at temperatures between 120 F and 250 F 177.1520 – Olefin Polymers 178.2010 – Antioxidants and/or stabilizers for polymers.
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 s not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
14	**BISPHENOL A (BPA)**	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.
15	**BSE/TSE**	Y				The material supplier has reviewed the raw materials used in the formulation of this resin. These raw materials do not contain any components of animal origin, and our supplier does not add any materials of animal origin. Therefore, our supplier has declared that the Granuflex resin does not contain animal derived components and hence is free from TSE risk.
16	**California Prop 65**	Y				The supplier of this raw material confirms this material does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65. Reformulation, use, or processing of this material may affect its composition and require re-evaluation.
17	**Canadian WHMIS INGREDIENT DISCLOUSRE 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, 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				No restricted substances are intentionally added or expected as process impurities above corresponding 0.1% threshold limits. (.01% for lead).
25	**Drug Master File**	Y				DMF 021124 and DMF 022698 at CDER, and BBMF 010869 and BBMF 013612 at CBER.
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**			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 ammendments**			N/A		Our Supplier has not indicated if this material meets these standards.
33	**EU MDR**				See Comment	The material supplier confirms this product's composition, substances listed in the 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, are not known to be present above the declaration threshold.
34	**EU-Food Contact (EC) No 1935/2004**				See Comment	Regulation (EU) 10/2011 + amending Regulations, the monomers used for the manufacture of the polymers used in the RENOLIT products covered by this TAIS have been approved for food contact. Some products may contain (traces of) an additive (CAS Registration Nr. 02082-79-3) with a SML = 6 mg/kg (fatty food).

35	**EU-Pharmacopeia (7th Edition)**				See Comment	The product's contact layer meets the test requirements of the current Edition of the European Pharmacopoeia, Chapter 3.1.5 As a whole, the product conforms to the following chapters: • PhEur Chapter 2.6.14 – Bacterial endotoxins • PhEur Chapter 5.2.8 – TSE/BSE • PhEur Chapter 5.20 – Metal Residues • Chapter 3.1.13
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				GMOs are not used in the manufacture or formulation of this product.
40	**GHS**	Y				This mixture is not classified according to US-GHS.
41	**Gluten-Free**	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.
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)**	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
44	**International Inventories**	Y				AS far as our knowledge this product is Not listed/Not regulated.
45	**ISO 10993-1**	Y				Material complies with cytotoxicity, sensitization, and intracutaneous reactivity.

46	**ISO 10993-10**	Y				The extracts of the test article of the Granuflex resin elicited no reaction at the challenge following an induction phase. As defined by the scoring system of Kligman, this is a Grade I reaction and the test article is classified as having weak allergenic potential. Based on the criteria of the protocol, a Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
47	**ISO 10993-11**	Y				According to present knowledge, no harmful effect at adequate use of such products. The various RENOLIT formulations have been thoroughly tested, chemically and biologically on amongst others for the following: - Acute systemic toxicity (acc. to ISO 10993-11) - no acute systemic Toxicity.
48	**ISO 10993-12**			N/A		This material has not be tested against these standards to our knowledge.
49	**ISO 10993-18, EXTRACTABLES TESTING**	Y				The material supplier has conducted extractable and chemical migration testing on a gamma irradiated sample of this material. The test report is available upon request.
50	**ISO 10993-2**			N/A		This material has not be tested against these standards to our Knowledge.
51	**ISO 10993-3**			N/A		This material has not be tested against these standards to our Knowledge.
52	**ISO 10993-4**	Y				The test article is considered non-hemolytic based on the test methods employed.
53	**ISO 10993-5**	Y				This material has not be tested against these standards to our Knowledge.
54	**ISO 10993-6**	Y				The test results indicate that the test article does not demonstrate any remarkable difference as compared to control site implants.

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 used in 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	**Natrual Rubber**	Y				Not intentionally used in the manufacture or formulation of this product.
61	**Nitrosamines**	Y				Not intentionally added during 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	**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.
67	**Other Substance/compounds**				See Comment	None listed at this time.
68	**Ozone Depleting Substances**	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.
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				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. Due to the absence of use of these substances, we do not evaluate for them.
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 (Perflouroctanoic acid)**	Y				Not intentionally added during the manufacture or formulation of this product.
74	**PFOS (Perflouroctane sulfonate)**	Y				Not intentionally added during the manufacture or formulation of this product.

75	**Phthalates:** **Dibutyl phthalate** **Dioctyl phthalate (DEHP) Di-isononyl phthalateDimethyl 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.
76	**REACH**	Y				The material supplier indicates no substances as 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 above 0.1% 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 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. Any trace amounts of these substances would not be expected to be above the regulated thresholds.
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				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				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)**			N/A		This material has not been tested against these standards to our knowledge.
84	**US Pharmacopeia Class VI**			N/A		This material has not been tested against these standards to our knowledge.
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**	Y				The tested formulation meets the test-requirements as described in USP28/NF20, Edition 2006, General Chapter <661> CONTAINERS, Physico-Chemical Tests – Plastics.
89	**USP 665 (Single - use systems (SUS) & the risk associated with extractable & leachables (E&L)**					This material has not been tested against these standards to our knowledge.
90	**USP 85 (Endotoxin)**			N/A		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)**	Y				According to present knowledge, no harmful effect at adequate use of such products. The various RENOLIT formulations have been thoroughly tested, chemically and biologically on amongst others for the following: - cytotoxicity (acc. to ISO 10993-5, USP<87> - non-cytotoxic;
93	**USP 88**	Y				The material supplier has declared that a sample of this material was tested in accordance with USP <88> biological reactivity tests, in vivo; the test article was found to meet the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 C.
94	**Volatile Organic Compounds (VOCs)**	Y				Not used in the manufacture or formulation of this product.
	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

95						confirms that they do not contain any substances listed in Annex II of this directive (2002/96/EC) as an intentional ingredient.