

**Material Code M0114**

**Revision 00**

**Type** SI  
**Brand name** LR 3003/ 10-80 ShA  
**Supplier** WACKER ELASTOSIL

**Sterilization Stability:**

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	Up to 50 kGy
Ethylene Oxyde	YES	-

**Biocompatibility Data:**

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	-	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Implantation	YES	ISO 10993-5/6	-
Hæmocompatibility	YES	ISO 10993-4	-

**Main Regulatory Compliances:**

	<u>Compliant</u>	<u>Comments</u>
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
European Directive 2012/19/UE - WEEE	YES	Not used in the manufacturing process
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

**Technical Characteristics:**

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	1.07 -> 1.16g/cm3	DIN EN ISO 1183-1 A	Depending of the Hardness
Color	Natural	-	-
Hardness	12 -> 76 ShA	DIN 53505	-
Other mechanical property 1	4.10 -> 7.4 N/mm2	DIN 53504 S 1	Tensile strength, depending of the Hardness
Other mechanical property 2	860% -> 210%	DIN 53504 S 1	Elongation at break, depending of the Hardness
Other mechanical property 3	10/20/30/70/80	-	Hardness available (ShA)

<b>R&amp;D Validation</b>	GVA	<b>QA/RA Validation</b>	CGI
<b>Date</b>	12/05/17	<b>Date</b>	12/05/17

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promepla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promepla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.