

Material Code **M0317**

Revision **01**

Type PVC
Brand name NDG RB1/RB3/RB4/RB5
Supplier Medical Grade PVC

Sterilization Stability:

| | Compliant | Comments |
|---------------------|-----------|----------|
| Gamma Sterilization | YES | - |
| Ethylene Oxide | YES | - |

Biocompatibility Data:

| | Compliant | Standard | Comments |
|---|-----------|--------------|----------|
| USP Class VI | YES | USP | - |
| 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 | - |
| Haemocompatibility | YES | ISO 10993-4 | - |

Main Regulatory Compliances:

| | Compliant | Comments |
|---|-----------|--|
| BPA | YES | Not used in the manufacturing process |
| European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2 | YES | Not used in the manufacturing process |
| European Pharmacopoeia | YES | 3.1.1.1. |
| Latex or Natural Rubber | YES | Not used in the manufacturing process |
| Phthalates | YES | Not used in the manufacturing process (can contain residual DEHP < 0.1%) |
| 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:

| | Value | Measuring Method | Comments |
|-----------|--------------------|------------------|---|
| Extrusion | YES | - | - |
| Density | 1.17 to 1.24 g/cm3 | ISO 1183 | RB1:1.24 - RB3:1.21 - RB4:1.20 - RB5:1.17 |
| Hardness | Depending Hardn. | ISO 868 | RB1: 81->92 ±2 - RB3: 75±2 - RB4 : 70±2 - RB5: 60±2 |

| | | | |
|---------------------|--|-----------------------|--|
| R&D Validation Date | | QA/RA Validation Date | |
|---------------------|--|-----------------------|--|

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.