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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 15812.1-2005

**Catheters other than intravascular catheters -- Part 1: Test
methods for common for properties**

(English Translation)

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Foreword

This Part of GB/T 15812 identically uses EN 1618.1997 Catheters other than intravascular catheters - Test methods for common properties.

The title for GB/T 15812 is Catheters other than intravascular catheters. It consists of the following parts.

- Part 1. Test methods for common properties;
- Part 2. Flexible polymeric tubes for medical use - Physical performance test method.

This Part replaces the test methods other than the method for bending resistance test in GB/T 15812-1995. The test items and methods specified in this Part are greatly different from GB/T 15812-1995 so it is basically not comparable.

Annex A, Annex B, Annex C, Annex D, Annex E and Annex F are normative.

This Part was proposed by State Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee on Medical Infusion Equipment of Standardization Administration of China.

Main drafting organization of this Part. Shandong Medical Equipment Product Quality Inspection Center, Jinan Medical Silicone Rubber Products Factory.

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Catheters other than intravascular catheters -

Part 1. Test methods for common properties

1 Scope

This Part of GB/T 15812 specifies test methods for common properties for catheters as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of catheter properties.

This Part is not applicable to intravascular catheters.

2 Test methods and results

The test methods are given in annexes A to F and results shall be expressed as, e.g.,

"Corrosion test according to GB/T 15812.1. No sign of corrosion".

Unless otherwise specified, tolerances on all variables in the test methods shall be $\pm 10\%$.

Annex F

(Normative)

Test method for security of connectors

F.1 Test for separation

The connector(s) are assembled in accordance with the manufacturer's instructions. A tensile force is applied and the assembled connection inspected for separation.

F.2 Apparatus

Tensile testing apparatus, capable of exerting a force of greater than 15 N.

F.3 Procedure

Assemble the connectors in accordance with the manufacturer's instructions.

Fix the assembled connectors in the tensile test apparatus (using an appropriate fixture to avoid deforming the connector, if necessary).

Apply a tensile force, as specified in the product standard, at a testing speed of 500 mm/min, Inspect the assembled connectors for separation.

F.4 Test report

The test report shall include the following information.

- a) identity of the catheter;
 - b) identity of the connector(s);
 - c) force applied, in newtons and whether the connectors separated.
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