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Specification for
**Sets of sterile intravascular radiographic
diagnostic catheters and associated
equipment for single use**

Jeux de cathéters diagnostiques radiographiques intravasculaires stériles
et équipements associés à usage unique

Sterile, intravaskuläre, radiografische Diagnosekathetersätze und dazugehörige
Teile zur einmaligen Verwendung

British Standards Institution

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Foreword

This British Standard was prepared at the request of the Department of Health and Social Security and was authorized by the BSI Surgical Instruments and Medical Appliances Industry Standards Committee.

The purpose of this standard has been to deal with basic requirements for sterile intravascular radiographic diagnostic catheters for single use, more particularly from the standpoint of those design features which affect the safety of the patient and size designation. Unnecessary details which might prove restrictive in the development of design have been avoided, but it should be remembered that the constituents of injectible radiographic materials may change and they may have a detrimental effect on the catheter. Care should therefore be taken when using new radiographic materials.

Although provision has been made for marking with the words 'radio-opaque', where applicable, radio-opacity has not been made a mandatory requirement since such limitation may impose restriction on the choice of material at the expense of strength and consequent performance of the product under stress.

Consideration is presently being given to the development of a revised method for assessing the radio-opacity of medical devices such as catheters. The determination of radio-opacity has therefore been omitted from this standard until such time as the revised method of test is available.

Certification. Attention is drawn to the certification facilities described on the inside back cover of this standard.