

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.****CE 512338**

Issued To:

**Arrow International, Inc.  
(subsidiary of Teleflex, Incorporated)  
2400 Bernville Road  
Reading  
Pennsylvania  
19605  
USA**

In respect of:

**Balloon Wedge Pressure Catheters and Kits**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2007-04-01**Date: **2019-02-18**Expiry Date: **2022-03-31**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 512338

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Finished Goods Product Number	Device Description
AI-07025	5 Fr 80 cm Double-Lumen Balloon Wedge Pressure Catheter
AI-07026	6 Fr 110 cm Double-Lumen Balloon Wedge Pressure Catheter
AI-07027	7 Fr 110 cm Double-Lumen Balloon Wedge Pressure Catheter
AI-07121	4 Fr 60 cm Balloon Wedge Pressure Catheter
AI-07122	4 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07123	5 Fr 60 cm Balloon Wedge Pressure Catheter
AI-07124	5 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07125	6 Fr 60 cm Balloon Wedge Pressure Catheter
AI-07126	6 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07126-J	6 Fr 90 cm Balloon Wedge Pressure Catheter
AI-07127	7 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07127-STC	7 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07128	8 Fr 110 cm Balloon Wedge Pressure Catheter
AI-07141	6 Fr 110 cm Double-Lumen Balloon Wedge Pressure Catheter
AI-07143	7 Fr 110 cm Double-Lumen Balloon Wedge Pressure Catheter

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## Certificate History

Date	Reference Number	Action
01 April 2007	10082075	First Issue – Transfer from another notified body
29 September 2010	10118043	Addition of back up sterilization facility - Sterigenics in Charlotte, North Carolina
26 March 2012	10133585	Certificate Renewal Revision of the information into a general product description format.
16 January 2014	10144870	Transfer of manufacturing activities from Mount Holly, New Jersey to Chelmsford, Massachusetts.
25 April 2014	10146198	Change to EtO sterilization release from BIs to parametric release at Sterigenics Charlotte, North Carolina and Sterigenics Santa Teresa, New Mexico
25 May 2016	10161773	Change affecting Tyvek ®1073 B and Tyvek® 1059B packaging materials - all product codes are affected.
28 March 2017	10169010	Certificate renewal and 'smart' numbering was replaced by listing each individual finished good number.
Current	7780599	Traceable to NB 0086.

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