

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 699333**
Date: **2020-12-01**
Issued To: **Arrow International LLC**
Subsidiary of Teleflex Incorporated
3015 Carrington Mill Blvd.
Morrisville
North Carolina
27560
USA

Date	Reference Number	Action
11 June 2020	9645608	First Issue. Mirror certificate to CE 511137.
Current	9731526	Certificate Renewal. Removed Stitch cutter, dressing commercial, drapes and ultrasound covers, surgical instruments, surgical apparel, cables, controlled stroke syringe, gauze pads, and sponges from Class Is device table as they are not CE marked separately. Added Class Is devices specifically to the scope statement. Added EID, RIC, and trauma catheters to scope and Class IIa device table. Change Celestica Oregon LLC and Custom Wire Technologies to crucial suppliers. Add LEK a Sandoz Company and Medichem S.A. as crucial suppliers.

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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