

# EC Certificate - Full Quality Assurance System

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

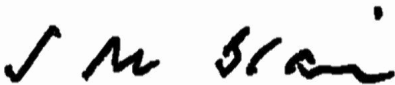
**No.** CE 02054  
**Issued To:** **Millar Inc.**  
**6001-A Gulf Freeway**  
**Houston**  
**Texas**  
**77023**  
**USA**

In respect of:

**The design and manufacture of sterile catheter mounted pressure transducers, and associated control units.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **1998-08-24**

Date: **2018-08-03**

Expiry Date: **2023-08-23**

...making excellence a habit.™

Page 1 of 1

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.

# EC Certificate - Full Quality Assurance System

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

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 02054**  
Date: **2018-08-03**  
Issued To: **Millar Inc.**  
**6001-A Gulf Freeway**  
**Houston**  
**Texas**  
**77023**  
**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	<b>EU Representative</b>
Steritec, Inc 1705 Enterprise St, Athens Texas 75751 USA	<b>ETO Sterilization</b>

...making excellence a habit.™

# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 02054**  
 Date: **2018-08-03**  
 Issued To: **Millar Inc.  
 6001-A Gulf Freeway  
 Houston  
 Texas  
 77023  
 USA**

Date	Reference Number	Action
24 August 1998		First issue
20 November 1998		Change of scope
05 February 1999		Change of scope
17 February 2004		Five years renewal Changes to List of Sub-contractors: Addition of MicroPaq and TriVirix as Manufacturing Sub-contractors New certificate format
20 August 2008	7243163	Certificate renewal Changes to the list of significant subcontractors: Removal of MicroPaq, TriVirix, Ethox Corp, NAMSA Inc at 2261 Tracy Road, Northwood, NAMSA Inc at PO 71970, Cincinnati.
22 August 2013	7982551	Certificate renewal Change of scope to 'The design and manufacture of sterile catheter mounted pressure and velocity transducers, and associated control units' Addition of 'EMERGO EUROPE' as EU Representative.

# EC Certificate - Full Quality Assurance System Certificate History

**Certificate No:** CE 02054  
**Date:** 2018-08-03  
**Issued To:** Millar Inc.  
 6001-A Gulf Freeway  
 Houston  
 Texas  
 77023  
 USA

Date	Reference Number	Action
17 July 2014	8184301	Change of company name from 'Millar Instruments Inc.' to 'Millar Inc.'
18 April 2017	8718613	Removal of velocity transducers from the scope and change of Emergo Europe's address from Molenstraat 15, 2513 BH The Hague, Netherlands to Prinsessegracht 20, 2514 AP The Hague, Netherlands.
Current	8892474	Renewal