

# EC Certificate - Full Quality Assurance System

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

**No.****CE 598543****Issued To:****Bracco Injeneering S.A.  
Avenue de Sévelin 46  
CH-1004 Lausanne  
Switzerland**

In respect of:

**The design and manufacture of contrast media injection systems and associated sterile disposables.**

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-07-18**

Date: **2019-10-04**

Expiry Date: **2024-05-26**

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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.

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## Supplementary Information to CE 598543

Issued To:

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NBOG code(s)	Device description	Intended purpose
<b>Class IIb</b>		
MD 1101 MDS 7010	Contrast media injection systems	Intended for administration of contrast media to human subjects while undergoing CT, or MRI examination
<b>Class IIa</b>		
MD 0102	Sterile Disposables for Contrast media injection systems	NA for class IIa devices

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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.

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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 598543**  
 Date: **2019-10-04**  
 Issued To: **Bracco Injeneering S.A.**  
**Avenue de Sévelin 46**  
**CH-1004 Lausanne**  
**Switzerland**

Subcontractor:	Service(s) supplied
ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie Minnesota 55344 USA	Manufacture
Bytec Medizintechnik GmbH Hermann-Hollerith-Str. 11D Eschweiler 52249 Germany	Manufacture
Coeur, Inc. 209 Creekside Drive Washington North Carolina 27889 USA	Control of Sterilization Manufacture

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Subcontractor:	Service(s) supplied
LRE Medical GmbH Hofer Straße 5 86720 Nördlingen Germany	Manufacture
Medisize Ireland Ltd (T/A Phillips-Medisize Ireland) High Road Letterkenny Co. Donegal Ireland	Manufacture
Seleon GmbH Brauereistrasse 13 06847 Dessau-Rosslau Germany	Manufacture

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**Switzerland**

### Subcontractor:

### Service(s) supplied

Sterilization Services  
 5674 Eastport Boulevard  
 Richmond  
 Virginia  
 23231  
 USA

**ETO Sterilization**

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## Certificate History

Certificate No: **CE 598543**  
Date: **2019-10-04**  
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Date	Reference Number	Action
18 July 2013	7984840	First issue (following transfer from another Notified Body). Address change from 28 to 46 Avenue de Sévelin and name change from Swiss Medical Care S.A. to Bracco Injeneering S.A.
08 October 2014	8168474	Update the subcontractor address details to include T/A Phillips-Medisize Ireland. Add new subcontractors 'Bytec Medizintechnik GmbH, Hermann-Hollerith-Str. 11D, 52249 Eschweiler, Germany' and 'Coeur, Inc. 209, Creekside Drive Washington, North Carolina 27889, USA' for 'manufacture' and 'sterile manufacture' activity. Certificate renewal.
20 February 2019	8469169	Traceable to NB 0086. Administrative change to subcontractor activity type, 'Sterile Manufacture' to 'Manufacture' for Coeur, Inc.
Current	9787599	Renewal. Addition of significant subcontractor Seleon GmbH. Addition of device table. Administrative change to subcontractor activity type, addition of 'Control of sterilization' to Coeur, Inc. Addition of ETO sterilization subcontractor Sterilization Services.

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