

B BRAUN	Form	Document Nr.:	SA-FR02-M-5-1-14-000-2-H-EN
	EC DECLARATION OF CONFORMITY STERILE DEVICES	Revision date:	30-08-2018
Chasseneuil		Creation date:	17-11-2006
		Page:	1 of 1

EC Declaration of conformity Déclaration CE de conformité

According to Directive 93/42/EEC concerning Medical Devices

Conformément à la Directive 93/42/CEE relative aux Dispositifs Médicaux
et aux articles R5211-1 et suivants du Code de la Santé Publique

Manufacturer :

Fabricant

B. Braun Medical

26 rue Armengaud
92210 Saint-Cloud
France

Product Group :

Gamme de produit

Surecan® and Cytocan

Needles for implantable access ports

Manufacturing site :

Site de fabrication

B. Braun Medical Industries Sdn. Bhd - Bayan Lepas Free Industrial Zone
11900 PENANG - Malaysia

Conformity Assessment Procedure:

Procédure d'évaluation de la conformité : Conformément à l'annexe II.3 de la Directive 93/42/CEE

Classification :

Classification

According to annexe IX of the Directive 93/42/EEC

Conformément à l'annexe IX de la Directive 93/42/CEE

Class : IIa

Classe

Notified Body / Identification number : G-MED / 0459

Organisme Notifié / Numéro d'identification

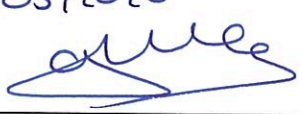
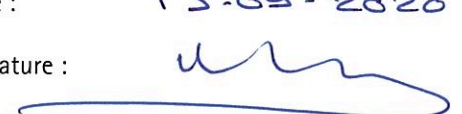
Address :

Adresse

1, rue Gaston Boissier - 75724 Paris Cedex 15

We hereby, **B. Braun Medical**, declare under sole responsibility, that the above mentioned product group meets all requirements of the Directive 93/42/EEC concerning medical devices which apply to it.

Nous, par la présente, **B. Braun Medical**, déclarons sous notre seule responsabilité, que le groupe de produit mentionné ci-dessus répond à toutes les exigences de la directive 93/42/CEE relative aux dispositifs médicaux qui lui sont applicables.

Regulatory Affairs Affaires réglementaires	Quality & Regulatory Affairs Qualité et Affaires réglementaires
Name / Nom : C. Trolie	Name / Nom : C. Baisneux
Date : 13/05/2020	Date : 13-05-2020
Signature : 	Signature : 

First issue : 06/02/2007

Date de création

RCS de Nanterre 562 050 856

au capital de 31 000 000 €

Code APE 3250 A

Revision : 13/05/2020

Date de révision

Adresse Postale

26, rue Armengaud

92210 Saint-Cloud

Valid until : 26/05/2024

Valide jusqu'au

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B BRAUN	Form	Document Nr.:	SA-FR02-M-5-1-14-000-3-G-EN
	PRODUCT LIST	Revision date:	30-08-2018
Chasseneuil		Creation date:	17-11-2006
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EC Declaration of conformity Déclaration CE de conformité



PRODUCT LIST

Liste de produits

PRODUCT RANGE <i>Gamme de produit</i>	Surecan® and Cytocan Needles for implantable access ports
Class <i>Classe</i>	Ila
Sterile / Non sterile <i>Stérile / Non stérile</i>	Sterile
Intended use <i>Usage revendiqué</i>	Needles with special bevel for implantable access ports
GMDN code <i>Code GMDN</i>	17701

REFERENCE <i>Référence</i>	PRODUCT <i>Produit</i>
See attached product list - Voir la liste de produits jointe	

Date of first EC-marking (or first lot number) : <i>Date de premier marquage CE (ou premier numéro de lot)</i>	Surecan® : manufacturing order : 5116258620 (September 2005) Cytocan : manufacturing order : 5123258664 (October 2005)
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Regulatory Affairs <i>Affaires réglementaires</i>	Quality & Regulatory Affairs <i>Qualité et Affaires réglementaires</i>
Name / Nom : <i>C. Trolé</i>	Name / Nom : <i>C. BOBENEU</i>
Date : <i>13/05/2020</i>	Date : <i>13-05-2020</i>
Signature : 	Signature : 

First issue : 06/02/2007
Date de création

Revision : 13/05/2020
Date de révision

EC DECLARATION OF CONFORMITY ANNEX (PAGE 1/4)

Surecan® needles for implantable access ports

REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04439953	Straight Surecan® 20G 40mm	Annexe II.3	n° 10488
04439998	Straight Surecan® 20G 70mm	Annexe II.3	n° 10488
04440000	Straight Surecan® 20G 90mm	Annexe II.3	n° 10488
04439848	Straight Surecan® 22G 30mm	Annexe II.3	n° 10488
04439414	Straight Surecan® 24G 25mm	Annexe II.3	n° 10488
04438000	Angled Surecan® 19G 15mm	Annexe II.3	n° 10488
04439430	Angled Surecan® 19G 20mm	Annexe II.3	n° 10488
04439406	Angled Surecan® 19G 25mm	Annexe II.3	n° 10488
04439929	Angled Surecan® 20G 15mm	Annexe II.3	n° 10488
04439937	Angled Surecan® 20G 20mm	Annexe II.3	n° 10488
04439945	Angled Surecan® 20G 25mm	Annexe II.3	n° 10488
04434862	Angled Surecan® 20G 35mm	Annexe II.3	n° 10488
04439813	Angled Surecan® 22G 15mm	Annexe II.3	n° 10488
04439821	Angled Surecan® 22G 20mm	Annexe II.3	n° 10488
04439830	Angled Surecan® 22G 25mm	Annexe II.3	n° 10488
04434870	Angled Surecan® 22G 35mm	Annexe II.3	n° 10488
04448286	Winged Surecan® 19G 15mm	Annexe II.3	n° 10488
04448294	Winged Surecan® 19G 20mm	Annexe II.3	n° 10488
04448308	Winged Surecan® 19G 25mm	Annexe II.3	n° 10488
04448332	Winged Surecan® 20G 15mm	Annexe II.3	n° 10488
04448340	Winged Surecan® 20G 20mm	Annexe II.3	n° 10488
04448359	Winged Surecan® 20G 25mm	Annexe II.3	n° 10488
04448367	Winged Surecan® 20G 30mm	Annexe II.3	n° 10488
04448375	Winged Surecan® 22G 12mm	Annexe II.3	n° 10488
04448383	Winged Surecan® 22G 15mm	Annexe II.3	n° 10488
04448391	Winged Surecan® 22G 20mm	Annexe II.3	n° 10488
04448405	Winged Surecan® 22G 25mm	Annexe II.3	n° 10488

EC DECLARATION OF CONFORMITY

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Surecan® needles for implantable access ports

REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
03448340	Winged Surecan® LP 20G 20mm	Annexe II.3	n° 10488
03448383	Winged Surecan® LP 22G 15mm	Annexe II.3	n° 10488
04448430	Winged Surecan® with Y-site 19G 20mm	Annexe II.3	n° 10488
04448448	Winged Surecan® with Y-site 19G 25mm	Annexe II.3	n° 10488
04448472	Winged Surecan® with Y-site 20G 15mm	Annexe II.3	n° 10488
04448480	Winged Surecan® with Y-site 20G 20mm	Annexe II.3	n° 10488
04448499	Winged Surecan® with Y-site 20G 25mm	Annexe II.3	n° 10488
04448529	Winged Surecan® with Y-site 22G 15mm	Annexe II.3	n° 10488
04448537	Winged Surecan® with Y-site 22G 20mm	Annexe II.3	n° 10488
04448545	Winged Surecan® with Y-site 22G 25mm	Annexe II.3	n° 10488
04448553	Winged Surecan® with Y-site 22G 30mm	Annexe II.3	n° 10488

Cytocan needles for implantable access ports

REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04438035	Cytocan 19G 15mm	Annexe II.3	n° 10488
04438019	Cytocan 19G 20mm	Annexe II.3	n° 10488
04438027	Cytocan 19G 25mm	Annexe II.3	n° 10488
04439759	Cytocan 20G 15mm	Annexe II.3	n° 10488
04439767	Cytocan 20G 20mm	Annexe II.3	n° 10488
04439775	Cytocan 20G 25mm	Annexe II.3	n° 10488
04439694	Cytocan 22G 15mm	Annexe II.3	n° 10488
04439635	Cytocan 22G 20mm	Annexe II.3	n° 10488
04439686	Cytocan 22G 25mm	Annexe II.3	n° 10488

EC DECLARATION OF CONFORMITY
ANNEX (PAGE 3/4)
Surecan® needles for implantable access ports

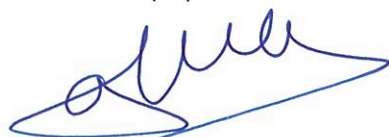
REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04439953-03	Straight Surecan® 20G 40mm	Annexe II.3	n° 10488
04439998-03	Straight Surecan® 20G 70mm	Annexe II.3	n° 10488
04440000-03	Straight Surecan® 20G 90mm	Annexe II.3	n° 10488
04439848-03	Straight Surecan® 22G 30mm	Annexe II.3	n° 10488
04439414-03	Straight Surecan® 24G 25mm	Annexe II.3	n° 10488
04438000-03	Angled Surecan® 19G 15mm	Annexe II.3	n° 10488
04439430-03	Angled Surecan® 19G 20mm	Annexe II.3	n° 10488
04439406-03	Angled Surecan® 19G 25mm	Annexe II.3	n° 10488
04439929-03	Angled Surecan® 20G 15mm	Annexe II.3	n° 10488
04439937-03	Angled Surecan® 20G 20mm	Annexe II.3	n° 10488
04439945-03	Angled Surecan® 20G 25mm	Annexe II.3	n° 10488
04434862-03	Angled Surecan® 20G 35mm	Annexe II.3	n° 10488
04439813-03	Angled Surecan® 22G 15mm	Annexe II.3	n° 10488
04439821-03	Angled Surecan® 22G 20mm	Annexe II.3	n° 10488
04439830-03	Angled Surecan® 22G 25mm	Annexe II.3	n° 10488
04434870-03	Angled Surecan® 22G 35mm	Annexe II.3	n° 10488
04448286-03	Winged Surecan® 19G 15mm	Annexe II.3	n° 10488
04448294-03	Winged Surecan® 19G 20mm	Annexe II.3	n° 10488
04448430-03	Winged Surecan® 19G 20mm with Y-site	Annexe II.3	n° 10488
04448308-03	Winged Surecan® 19G 25mm	Annexe II.3	n° 10488
04448448-03	Winged Surecan® 19G 25mm with Y-site	Annexe II.3	n° 10488
04448332-03	Winged Surecan® 20G 15mm	Annexe II.3	n° 10488
04448472-03	Winged Surecan® 20G 15mm with Y-site	Annexe II.3	n° 10488
04448340-03	Winged Surecan® 20G 20mm	Annexe II.3	n° 10488
04448480-03	Winged Surecan® 20G 20mm with Y-site	Annexe II.3	n° 10488
04448359-03	Winged Surecan® 20G 25mm	Annexe II.3	n° 10488
04448499-03	Winged Surecan® 20G 25mm with Y-site	Annexe II.3	n° 10488
04448367-03	Winged Surecan® 20G 30mm	Annexe II.3	n° 10488
04448375-03	Winged Surecan® 22G 12mm	Annexe II.3	n° 10488
04448383-03	Winged Surecan® 22G 15mm	Annexe II.3	n° 10488
04448529-03	Winged Surecan® 22G 15mm with Y-site	Annexe II.3	n° 10488
04448391-03	Winged Surecan® 22G 20mm	Annexe II.3	n° 10488
04448537-03	Winged Surecan® 22G 20mm with Y-site	Annexe II.3	n° 10488
04448405-03	Winged Surecan® 22G 25mm	Annexe II.3	n° 10488
04448545-03	Winged Surecan® 22G 25mm with Y-site	Annexe II.3	n° 10488
04448553-03	Winged Surecan® 22G 30mm with Y-site	Annexe II.3	n° 10488

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Cytocan needles for implantable access ports

REFERENCES	DESIGNATION	DIRECTIVE 93/42/EEC	EC CERTIFICATE
04438035-03	Cytocan 19G 15mm	Annexe II.3	n° 10488
04438019-03	Cytocan 19G 20mm	Annexe II.3	n° 10488
04438027-03	Cytocan 19G 25mm	Annexe II.3	n° 10488
04439759-03	Cytocan 20G 15mm	Annexe II.3	n° 10488
04439767-03	Cytocan 20G 20mm	Annexe II.3	n° 10488
04439775-03	Cytocan 20G 25mm	Annexe II.3	n° 10488
04439694-03	Cytocan 22G 15mm	Annexe II.3	n° 10488
04439635-03	Cytocan 22G 20mm	Annexe II.3	n° 10488
04439686-03	Cytocan 22G 25mm	Annexe II.3	n° 10488

Date : 13/05/2020



Christelle TROLESE
Adjoint Affaires Réglementaires
B. Braun Medical France – Site Chasseneuil