

<b>B   BRAUN</b>	Form	Document Nr.:	SA-FR02-M-5-1-14-000-2-H-EN
	<b>EC DECLARATION OF CONFORMITY STERILE DEVICES</b>	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 :** **B. Braun Medical**  
*Fabricant* 26 rue Armengaud  
92210 Saint-Cloud  
France

**Product Group :** **Surecan® Safety II**  
*Gamme de produit* Needles for implantable access ports

**Manufacturing site :** B. Braun Medical Industries Sdn. Bhd - Bayan Lepas Free Industrial Zone  
*Site de fabrication* 11900 PENANG - Malaysia

**Conformity Assessment Procedure:** According to annexe II.3 of the Directive 93/42/EEC  
*Procédure d'évaluation de la conformité :* Conformément à l'annexe II.3 de la Directive 93/42/CEE

**Classification :** According to annexe IX of the Directive 93/42/EEC  
*Classification* 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 :** 1, rue Gaston Boissier - 75724 Paris Cedex 15  
*Adresse*

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 <i>Affaires réglementaires</i>	Quality & Regulatory Affairs <i>Qualité et Affaires réglementaires</i>
Name / Nom : C. TROPEZ	Name / Nom : C. BOISNEU
Date : 13/05/2020	Date : 13-05-2020
Signature : 	Signature : 

First issue : 14/06/2011  
*Date de création*

Revision : 13/05/2020  
*Date de révision*

Valid until : 26/05/2024  
*Valide jusqu'au*

RCS de Nanterre 562 050 856  
au capital de 31 000 000 €  
Code APE 3250 A

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<b>B   BRAUN</b>	Form	Document Nr.:	SA-FR02-M-5-1-14-000-3-G-EN
	PRODUCT LIST	Revision date:	30-08-2018
		Creation date:	17-11-2006
		Page:	1 of 1
Chasseneuil			

## EC Declaration of conformity Déclaration CE de conformité



### PRODUCT LIST

*Liste de produits*

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

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

<b>Date of first EC-marking (or first lot number) :</b> <i>Date de premier marquage CE (ou premier numéro de lot)</i>	Manufacturing batch : 1E03258660 Date : May 2011.
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Regulatory Affairs <i>Affaires réglementaires</i>	Quality & Regulatory Affairs <i>Qualité et Affaires réglementaires</i>
Name / Nom : C. Trolise Date : 13/03/2020 Signature : 	Name / Nom : C. Baignewu Date : 13-05-2020 Signature : 

First issue : 14/06/2011  
*Date de création*

Revision : 13/05/2020  
*Date de révision*



**EC DECLARATION OF CONFORMITY – ANNEX**  
**Surecan® Safety II needles for implantable access ports**

REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
04447042	Surecan® Safety II 19G 12mm	Annex II.3	n° 10488
04447000	Surecan® Safety II 19G 15mm	Annex II.3	n° 10488
04447001	Surecan® Safety II 19G 20mm	Annex II.3	n° 10488
04447002	Surecan® Safety II 19G 25mm	Annex II.3	n° 10488
04447003	Surecan® Safety II 19G 32mm	Annex II.3	n° 10488
04447004	Surecan® Safety II 19G 38mm	Annex II.3	n° 10488
04447043	Surecan® Safety II 20G 12mm	Annex II.3	n° 10488
04447005	Surecan® Safety II 20G 15mm	Annex II.3	n° 10488
04447006	Surecan® Safety II 20G 20mm	Annex II.3	n° 10488
04447007	Surecan® Safety II 20G 25mm	Annex II.3	n° 10488
04447008	Surecan® Safety II 20G 32mm	Annex II.3	n° 10488
04447009	Surecan® Safety II 20G 38mm	Annex II.3	n° 10488
04447044	Surecan® Safety II 22G 12mm	Annex II.3	n° 10488
04447010	Surecan® Safety II 22G 15mm	Annex II.3	n° 10488
04447011	Surecan® Safety II 22G 20mm	Annex II.3	n° 10488
04447012	Surecan® Safety II 22G 25mm	Annex II.3	n° 10488
04447013	Surecan® Safety II 22G 32mm	Annex II.3	n° 10488
04447057	Surecan® Safety II with Caresite® Y 19G 12mm	Annex II.3	n° 10488
04447045	Surecan® Safety II with Caresite® Y 19G 15mm	Annex II.3	n° 10488
04447046	Surecan® Safety II with Caresite® Y 19G 20mm	Annex II.3	n° 10488
04447047	Surecan® Safety II with Caresite® Y 19G 25mm	Annex II.3	n° 10488
04447048	Surecan® Safety II with Caresite® Y 19G 32mm	Annex II.3	n° 10488
04447049	Surecan® Safety II with Caresite® Y 19G 38mm	Annex II.3	n° 10488
04447058	Surecan® Safety II with Caresite® Y 20G 12mm	Annex II.3	n° 10488
04447050	Surecan® Safety II with Caresite® Y 20G 15mm	Annex II.3	n° 10488
04447051	Surecan® Safety II with Caresite® Y 20G 20mm	Annex II.3	n° 10488
04447052	Surecan® Safety II with Caresite® Y 20G 25mm	Annex II.3	n° 10488
04447053	Surecan® Safety II with Caresite® Y 20G 32mm	Annex II.3	n° 10488
04447059	Surecan® Safety II with Caresite® Y 22G 12mm	Annex II.3	n° 10488
04447054	Surecan® Safety II with Caresite® Y 22G 15mm	Annex II.3	n° 10488
04447055	Surecan® Safety II with Caresite® Y 22G 20mm	Annex II.3	n° 10488
04447056	Surecan® Safety II with Caresite® Y 22G 25mm	Annex II.3	n° 10488

## EC DECLARATION OF CONFORMITY – ANNEX (Page 2 of 2)

### Surecan® Safety II needles for implantable access ports

REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
04447042-03	Surecan® Safety II 19G 12mm	Annex II.3	n° 10488
04447000-03	Surecan® Safety II 19G 15mm	Annex II.3	n° 10488
04447001-03	Surecan® Safety II 19G 20mm	Annex II.3	n° 10488
04447002-03	Surecan® Safety II 19G 25mm	Annex II.3	n° 10488
04447003-03	Surecan® Safety II 19G 32mm	Annex II.3	n° 10488
04447004-03	Surecan® Safety II 19G 38mm	Annex II.3	n° 10488
04447043-03	Surecan® Safety II 20G 12mm	Annex II.3	n° 10488
04447005-03	Surecan® Safety II 20G 15mm	Annex II.3	n° 10488
04447006-03	Surecan® Safety II 20G 20mm	Annex II.3	n° 10488
04447007-03	Surecan® Safety II 20G 25mm	Annex II.3	n° 10488
04447008-03	Surecan® Safety II 20G 32mm	Annex II.3	n° 10488
04447009-03	Surecan® Safety II 20G 38mm	Annex II.3	n° 10488
04447044-03	Surecan® Safety II 22G 12mm	Annex II.3	n° 10488
04447010-03	Surecan® Safety II 22G 15mm	Annex II.3	n° 10488
04447011-03	Surecan® Safety II 22G 20mm	Annex II.3	n° 10488
04447012-03	Surecan® Safety II 22G 25mm	Annex II.3	n° 10488
04447013-03	Surecan® Safety II 22G 32mm	Annex II.3	n° 10488
04447057-03	Surecan® Safety II with Caresite® Y 19G 12mm	Annex II.3	n° 10488
04447045-03	Surecan® Safety II with Caresite® Y 19G 15mm	Annex II.3	n° 10488
04447046-03	Surecan® Safety II with Caresite® Y 19G 20mm	Annex II.3	n° 10488
04447047-03	Surecan® Safety II with Caresite® Y 19G 25mm	Annex II.3	n° 10488
04447048-03	Surecan® Safety II with Caresite® Y 19G 32mm	Annex II.3	n° 10488
04447049-03	Surecan® Safety II with Caresite® Y 19G 38mm	Annex II.3	n° 10488
04447058-03	Surecan® Safety II with Caresite® Y 20G 12mm	Annex II.3	n° 10488
04447050-03	Surecan® Safety II with Caresite® Y 20G 15mm	Annex II.3	n° 10488
04447051-03	Surecan® Safety II with Caresite® Y 20G 20mm	Annex II.3	n° 10488
04447052-03	Surecan® Safety II with Caresite® Y 20G 25mm	Annex II.3	n° 10488
04447053-03	Surecan® Safety II with Caresite® Y 20G 32mm	Annex II.3	n° 10488
04447059-03	Surecan® Safety II with Caresite® Y 22G 12mm	Annex II.3	n° 10488
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04447056-03	Surecan® Safety II with Caresite® Y 22G 25mm	Annex II.3	n° 10488

Date: 13/05/2020



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