

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
Creation date:		17-11-2006	
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Chasseneuil			

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. Troler	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 BRAUN	Form	Document Nr.:	SA-FR02-M-5-1-14-000-3-G-EN
	Chasseneuil	PRODUCT LIST	Revision date:
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® Safety II 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 - <i>Voir la liste de produits jointe</i>	

Date of first EC-marking (or first lot number) : <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 : <i>C. Trolise</i>	Name / Nom : <i>C. Baisnewu</i>
Date : <i>13/05/2020</i>	Date : <i>13-05-2020</i>
Signature : 	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
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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