

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

B. BRAUN MEDICAL

26 rue Armengaud

92210 SAINT-CLOUD FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Aiguilles à biseau spécial pour chambres à cathéter implantables - Surecan® et Cytocan®

Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P183502 / P601745, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

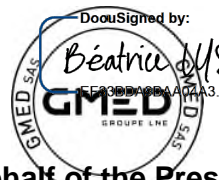
GMED certifies that, on the basis of the results contained in the file referenced P183502 / P601745, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : March 31st, 2020 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



**On behalf of the President
Béatrice LYS
Technical Director**



Addendum au certificat n° 10488 rev. 13 page 1/1
Addendum of the certificate n° 10488 rev. 13
Dossier / File N° P183502 / P601745

Identification des dispositifs / Identification of devices

Aiguilles à biseau spécial pour chambres à cathéter implantables - Surecan® et Cytocan®
Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®

**Les produits couverts par ce certificat sont référencés sur la liste des produits
authentifiée par GMED en date du 24 mars 2020 (6 pages)**
*The products covered by this certificate are listed on the manufacturer's list of products
authenticated by GMED on March 24th, 2020 (6 pages)*

Identification des sites et activités / Identification of locations and activities

- **26 rue Armengaud – 92210 SAINT-CLOUD – France :**
*Siège social – Responsable de la mise sur le marché / Headquarters – Legal
manufacturer*
- **30 avenue des Temps Modernes - 86360 CHASSENEUIL-DU-POITOU – France :**
Conception / Design

GMED	0459
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DocuSigned by:

Béatrice LYS

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On behalf of the President
Béatrice LYS
Technical Director

IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)

(PAGE 1/6)

Aiguilles à biseau spécial pour chambres à cathéter implantables Surecan® et Cytocan® Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®			
REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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
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

GIMED (0459) reconnaît que son certificat CE
est valide pour les dispositifs médicaux décrits
le 26 mars 2020
GIMED (0459) recognizes that its EC certificate
is valid for the medical devices listed

DocuSigned by:

Aysel SAVAS

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Page 1 of 6

IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)
(PAGE 2/6)

Aiguilles à biseau spécial pour chambres à cathéter implantables Surecan® et Cytocan® Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®			
REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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
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
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

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Ayel SAVAS

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Page 2 of 6

IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)
 (PAGE 3/6)

Aiguilles à biseau spécial pour chambres à cathéter implantables Surecan® et Cytocan® Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®			
REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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

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IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)
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Aiguilles à biseau spécial pour chambres à cathéter implantables Surecan® et Cytocan® Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®			
REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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
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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
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04448359-03	Winged Surecan® 20G 25mm	Annexe II.3	n° 10488

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IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)
(PAGE 5/6)

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REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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
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
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04439635-03	Cytocan 22G 20mm	Annexe II.3	n° 10488
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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

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26 mars 2020
GMED (0459) recognizes that its EC certificate
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Ayél SAVAS

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IDENTIFICATION DU (DES) DISPOSITIFS / IDENTIFICATION OF DEVICE(S)
 (PAGE 6/6)

Aiguilles à biseau spécial pour chambres à cathéter implantables Surecan® et Cytocan® Special bevelled needles for implantable vascular access systems Surecan® and Cytocan®			
REFERENCES	DESIGNATION	DIRECTIVE 93/42/CEE	EC CERTIFICAT
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
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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
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04447049-03	Surecan® Safety II with Caresite® Y 19G 38mm	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: 23/03/2020


Catherine BOISMENU
 CoE Chasseneuil, Deputy Director in charge of Quality and delegated Regulatory Affairs
 B.Braun Medical

 GMED (0459) reconnaît que son certificat CE
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 26 mars 2020
 GMED (0459) recognizes that its EC certificate
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