



**ATTESTATION / CERTIFICATE N° 10488 rev. 13**

**Délivrée à Paris le 31 mars 2020**

*Issued in Paris on March 31st, 2020*

## **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.**

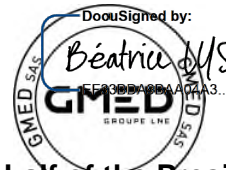
*GMED certifies that, on the basis of the results contained in the file referenced P183502 / P601745, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4*

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**

<b>GMED</b>	<b>0459</b>
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*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®			
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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

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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DocuSigned by:

Aye SAVAS

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## 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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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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(PAGE 4/6)

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04439998-03	Straight Surecan® 20G 70mm	Annexe II.3	n° 10488
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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
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26 mars 2020

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

(PAGE 6/6)

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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
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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

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