

**Către Agenția Medicamentului
și Dispozitivelor Medicale**

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 08/10 din 09.10.2023

Solicitantul „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 73 73, e-mail office@gbg.md, solicit respectuos înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale ale producătorului **AMPLITUDE SAS**, pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Référence Reference	Désignation Designation	Etude Study
1-0200501	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 1 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 1	ET106-002
1-0200502	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 2 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 2	ET106-002
1-0200503	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 3 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 3	ET106-002
1-0200504	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 4 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 4	ET106-002
1-0200505	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 5 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 5	ET106-002
1-0200506	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 6 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 6	ET106-002
1-0200507	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 7 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 7	ET106-002
1-0200500	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 0 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 0	ET106-001
1-0200508	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 8 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 8	ET106-001
1-0200401	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 1 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 1	ET106-002
1-0200402	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 2 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 2	ET106-002
1-0200403	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 3 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 3	ET106-002
1-0200404	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 4 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 4	ET106-002
1-0200405	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 5 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 5	ET106-002
1-0200406	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 6 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 6	ET106-002
1-0200407	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 7 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 7	ET106-002
1-0200400	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 0 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 0	ET106-001

1-0200408

Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 8
SCORE® tibial base plate for mobile bearing insert - HA coated - cementless –
Size 8

ET106-001

Se anexează următoarele acte:*Notificarea pentru înregistrarea dispozitivelor medicale;**Declarația pe proprie răspundere;**Declarația de conformitate;**Scrisoarea de Autorizare;**Certificat CE.*

Data _____

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

**Către Agenția Medicamentului
și Dispozitivelor Medicale**

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 08/10 din 09.10.2023

Solicitantul „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 73 73, e-mail office@gbg.md, solicit respectuos înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale ale producătorului **AMPLITUDE SAS**, pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Référence Reference	Désignation Designation	Etude Study
1-0200501	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 1 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 1	ET106-002
1-0200502	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 2 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 2	ET106-002
1-0200503	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 3 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 3	ET106-002
1-0200504	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 4 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 4	ET106-002
1-0200505	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 5 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 5	ET106-002
1-0200506	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 6 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 6	ET106-002
1-0200507	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 7 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 7	ET106-002
1-0200500	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 0 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 0	ET106-001
1-0200508	Embase tibiale SCORE® pour insert mobile - A cimenté - Taille 8 SCORE® tibial base plate for mobile bearing insert - Cemented - Size 8	ET106-001
1-0200401	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 1 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 1	ET106-002
1-0200402	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 2 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 2	ET106-002
1-0200403	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 3 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 3	ET106-002
1-0200404	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 4 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 4	ET106-002
1-0200405	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 5 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 5	ET106-002
1-0200406	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 6 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 6	ET106-002
1-0200407	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 7 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 7	ET106-002
1-0200400	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment - Taille 0 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless - Size 0	ET106-001

1-0200408

Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 8
SCORE® tibial base plate for mobile bearing insert - HA coated - cementless –
Size 8

ET106-001

Se anexează următoarele acte:*Notificarea pentru înregistrarea dispozitivelor medicale;**Declarația pe proprie răspundere;**Declarația de conformitate;**Scrisoarea de Autorizare;**Crtificat CE.*

Data _____

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către
solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: „GBG-MLD” SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2.

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru înregistrarea dispozitivelor producătorului **AMPLITUDE SAS**, pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Référence Reference	Désignation Designation	Etude Study
1-0200501	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 1 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 1	ET106-002
1-0200502	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 2 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 2	ET106-002
1-0200503	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 3 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 3	ET106-002
1-0200504	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 4 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 4	ET106-002
1-0200505	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 5 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 5	ET106-002
1-0200506	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 6 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 6	ET106-002
1-0200507	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 7 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 7	ET106-002
1-0200500	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 0 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 0	ET106-001
1-0200508	Embase tibiale SCORE [®] pour insert mobile - A cimenté - Taille 8 SCORE [®] tibial base plate for mobile bearing insert – Cemented – Size 8	ET106-001
1-0200401	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 1 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 1	ET106-002
1-0200402	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 2 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 2	ET106-002
1-0200403	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 3 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 3	ET106-002
1-0200404	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 4 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 4	ET106-002
1-0200405	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 5 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 5	ET106-002
1-0200406	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 6 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 6	ET106-002
1-0200407	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 7 SCORE [®] tibial base plate for mobile bearing insert – HA coated - cementless – Size 7	ET106-002
1-0200400	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 0 SCORE [®] tibial base plate for mobile bearing insert - HA coated - cementless – Size 0	ET106-001
1-0200408	Embase tibiale SCORE [®] pour insert mobile - HAP - sans ciment – Taille 8 SCORE [®] tibial base plate for mobile bearing insert - HA coated - cementless – Size 8	ET106-001

Sunt autentice și corespund realității.

Cristina GUȚU, Șef Secție „GBG-MLD” SRL

Semnătura _____

Data _____



To: Medicines and Medical Devices Agency

We, **Amplitude SAS**, having a registered office at 11 cours Jacques Offenbach, 26 000 Valence, France, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as Authorized representative in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Valence, France

August 02, 2023



11, cours J. Offenbach
Zona d'activités Mozart II
26000 Valence - France
Tél. : +33 (0)4 75 41 87 41
Fax : +33 (0)4 75 41 87 42
Siret : 414 448 464 00050
AMPLITUDE[®]

Christian VILLOING
Directeur opérations commerciales internationales
International commercial operations Director

Mob: + 33 (0)6 42 46 02 04

Christian.VILLOING@amplitude-ortho.com



11, Cours Jacques Offenbach
26000 VALENCE
France

www.amplitude-ortho.com

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

AMPLITUDE

11 Cours Jacques Offenbach
Zone d'Activités Mozart 2
26000 VALENCE - FRANCE

Déclare sous son entière responsabilité que **les dispositifs médicaux** suivants :
*Declares under its sole responsibility that the following **medical devices**:*

Type de produit: <i>Product type</i>	Prothèse totale de Genou <i>Total Knee prosthesis</i>	Classe du produit <i>Product class</i>
Désignation du dispositif : Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment Condyle fémoral SCORE® sans conservation du LCP - A cimenter Embase tibiale SCORE® pour insert mobile - HAP - sans ciment Embase tibiale SCORE® pour insert mobile - A cimenter Insert mobile SCORE® Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - à cimenter Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter Composant fémoral SCORE® II – A cimenter Composant fémoral SCORE® II – Sans Ciment Insert tibial mobile SCORE® II Quille longue Allergy solution pour prothèse totale de Genou – A cimenter <i>Device designation</i> SCORE® femoral component PCL sacrificing – HA coated – Cementless SCORE® femoral component PCL sacrificing – Cemented SCORE® tibial base plate for mobile bearing insert – HA coated - cementless SCORE® tibial base plate for mobile bearing insert – Cemented SCORE® mobile bearing insert SCORE® Allergy Solution femoral component PCL sacrificing - Cemented SCORE® Allergy Solution tibial baseplate for mobile bearing insert – Cemented SCORE® II Femoral component - Cemented SCORE® II Femoral Component HA Coated Cementless SCORE® II Mobile Bearing Insert Allergy Solution extension stem for Total Knee prosthesis - Cmented		III Règle de classification <i>Classification rule</i> Règle 8 annexe IX directive 93/42/CE – article 1^{er} directive 2005/50/CE Rule 8 directive 93/42/EC - 1st article directive 2005/50/EC
Référence(s) : Voir liste ci-jointe. <i>Reference(s): See enclosed list.</i>		

- ✓ Satisfont aux dispositions du Code de la Santé Publique qui leur sont applicables,
Comply with the applicable provisions of the French public health code,
- ✓ Sont conformes aux exigences essentielles de l'Annexe I de la Directive 93/42/CEE.
Meet the essential requirements of Annexe I of Directive 93/42/EEC.
- ✓ Ne contiennent aucun composé d'origine animale et qu'aucun composé d'origine animale n'est utilisé lors de leur fabrication. Certains éléments de conditionnement peuvent avoir été en contact lors de leur fabrication avec les additifs d'origine animale. Ces additifs ont été traités de telle sorte qu'ils sont exclus du périmètre d'application du Règlement 722/12 du 08 Août 2012.
Do not contain any material from animal origin and are not manufactured using component from animal origin. Some packaging items may have been in contact during the manufacturing with additives from animal origin. These additives have been processed in a way that excludes them from the application of the Regulation 722/12 of August, 8th 2012.
- ✓ Ne sont pas soumis aux Exigences du point 7.4 de l'Annexe I de la directive 93/42/CEE introduisant des spécifications détaillées en ce qui concerne les exigences prévues pour les dispositifs médicaux incorporant comme partie intégrante une substance dérivée du sang humain.



AMPLITUDE°

DECLARATION CE DE CONFORMITE
EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Are not subject to the requirements of point 7.4 of the directive 93/42/EEC introducing detailed specifications as regards with the requirements with respect to medical devices manufactured integrating a substance derived from human blood.

- ✓ Ne sont pas soumis aux Exigences du point 7.4 de l'Annexe I de la directive 93/42/CEE introduisant des spécifications détaillées en ce qui concerne les exigences prévues pour les dispositifs médicaux incorporant comme partie intégrante une substance susceptible d'être considérée comme un médicament conformément à la Directive 2001/83/CE.

Are not subject to the requirements of point 7.4 of the directive 93/42/EEC introducing detailed specifications as regards with the requirements with respect to medical devices manufactured integrating a substance which may be considered a medicinal product in accordance with Directive 2001/83/EC.

Procédure d'évaluation de la conformité : Annexe II, Directive 93/42/CEE

Conformity assessment procedure: Annexe II, Directive 93/42/EEC

•Certificat Annexe II section 4 exclue <i>Certificate Annex II excluding section 4</i>	615308	•Certificat Annexe II.4 <i>Annex II.4 certificate</i>	615311 615314
BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands			
Délivré par : <i>Issued by:</i>	notified body 2797		

Le Directeur Qualité Affaires Réglementaires / Quality and Regulatory Affairs Director

Mireille LEMERY
ORL

Date de 1^{ère} déclaration CE de conformité / *First EC declaration of conformity issued on:* 2002-03-25

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :

2019-MAR-29

Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment

SCORE® femoral component PCL sacrificing – HA coated – Cementless

Référence Reference	Désignation Designation	Etude Study
1-0200101	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 1 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 1 RIGHT</i>	ET106-002
1-0200102	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 2 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 2 RIGHT</i>	ET106-002
1-0200103	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 3 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 3 RIGHT</i>	ET106-002
1-0200104	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 4 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 4 RIGHT</i>	ET106-002
1-0200105	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 5 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 5 RIGHT</i>	ET106-002
1-0200106	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 6 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 6 RIGHT</i>	ET106-002
1-0200107	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 7 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 7 RIGHT</i>	ET106-002
1-0200111	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 1 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 1 LEFT</i>	ET106-002
1-0200112	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 2 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 2 LEFT</i>	ET106-002
1-0200113	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 3 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 3 LEFT</i>	ET106-002
1-0200114	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 4 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 4 LEFT</i>	ET106-002
1-0200115	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 5 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 5 LEFT</i>	ET106-002
1-0200116	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 6 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 6 LEFT</i>	ET106-002
1-0200117	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 7 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated – Cementless – Size 7 LEFT</i>	ET106-002

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :

2019-MAR-29

Condyle fémoral SCORE® sans conservation du LCP - A cimenter

SCORE® femoral component PCL sacrificing – Cemented

Référence Reference	Désignation Designation	Etude Study
1-0200201	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 1 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 1 RIGHT</i>	ET106-002
1-0200202	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 2 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 2 RIGHT</i>	ET106-002
1-0200203	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 3 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 3 RIGHT</i>	ET106-002
1-0200204	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 4 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 4 RIGHT</i>	ET106-002
1-0200205	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 5 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 5 RIGHT</i>	ET106-002
1-0200206	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 6 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 6 RIGHT</i>	ET106-002
1-0200207	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 7 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 7 RIGHT</i>	ET106-002
1-0200211	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 1 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 1 LEFT</i>	ET106-002
1-0200212	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 2 GAUCHE <i>SCORE® Femoral component PCL sacrificing – Cemented – Size 2 LEFT</i>	ET106-002
1-0200213	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 3 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 3 LEFT</i>	ET106-002
1-0200214	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 4 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 4 LEFT</i>	ET106-002
1-0200215	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 5 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 5 LEFT</i>	ET106-002
1-0200216	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 6 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 6 LEFT</i>	ET106-002
1-0200217	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 7 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 7 LEFT</i>	ET106-002

DECLARATION CE DE CONFORMITE EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Embase tibiale SCORE® pour insert mobile - HAP - sans ciment *SCORE® tibial base plate for mobile bearing insert – HA coated - cementless*

Référence Reference	Désignation Designation	Etude Study
1-0200401	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 1 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 1</i>	ET106-002
1-0200402	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 2 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 2</i>	ET106-002
1-0200403	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 3 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 3</i>	ET106-002
1-0200404	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 4 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 4</i>	ET106-002
1-0200405	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 5 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 5</i>	ET106-002
1-0200406	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 6 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 6</i>	ET106-002
1-0200407	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 7 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 7</i>	ET106-002
1-0200400	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 0 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 0</i>	ET106-001
1-0200408	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 8 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 8</i>	ET106-001

Embase tibiale SCORE® pour insert mobile - A cimenter *SCORE® tibial base plate for mobile bearing insert – Cemented*

Référence Reference	Désignation Designation	Etude Study
1-0200501	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 1 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 1</i>	ET106-002
1-0200502	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 2 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 2</i>	ET106-002
1-0200503	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 3 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 3</i>	ET106-002
1-0200504	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 4 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 4</i>	ET106-002
1-0200505	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 5 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 5</i>	ET106-002
1-0200506	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 6 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 6</i>	ET106-002
1-0200507	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 7 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 7</i>	ET106-002
1-0200500	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 0 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 0</i>	ET106-001
1-0200508	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 8 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 8</i>	ET106-001

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Insert mobile SCORE®

SCORE® mobile bearing insert

Référence Reference	Désignation Designation	Etude Study
1-0200611	Insert mobile SCORE® – Taille 1 - Epaisseur 10 mm SCORE® mobile bearing insert – Size 1 - Thickness 10 mm	ET106-002 ET106-003
1-0200621	Insert mobile SCORE® – Taille 1 - Epaisseur 12 mm SCORE® mobile bearing insert – Size 1 - Thickness 12 mm	ET106-002 ET106-003
1-0200631	Insert mobile SCORE® – Taille 1 - Epaisseur 14 mm SCORE® mobile bearing insert – Size 1 - Thickness 14 mm	ET106-002 ET106-003
1-0200641	Insert mobile SCORE® – Taille 1 - Epaisseur 16 mm SCORE® mobile bearing insert – Size 1 - Thickness 16 mm	ET106-002 ET106-003
1-0200651	Insert mobile SCORE® – Taille 1 - Epaisseur 20 mm SCORE® mobile bearing insert – Size 1 - Thickness 20 mm	ET106-002 ET106-003
1-0200612	Insert mobile SCORE® – Taille 2 - Epaisseur 10 mm SCORE® mobile bearing insert – Size 2 - Thickness 10 mm	ET106-002 ET106-003
1-0200622	Insert mobile SCORE® – Taille 2 - Epaisseur 12 mm SCORE® mobile bearing insert – Size 2 - Thickness 12 mm	ET106-002 ET106-003
1-0200632	Insert mobile SCORE® – Taille 2 - Epaisseur 14 mm SCORE® mobile bearing insert – Size 2 - Thickness 14 mm	ET106-002 ET106-003
1-0200642	Insert mobile SCORE® – Taille 2 - Epaisseur 16 mm SCORE® mobile bearing insert – Size 2 - Thickness 16 mm	ET106-002 ET106-003
1-0200652	Insert mobile SCORE® – Taille 2 - Epaisseur 20 mm SCORE® mobile bearing insert – Size 2 - Thickness 20 mm	ET106-002 ET106-003
1-0200613	Insert mobile SCORE® – Taille 3 - Epaisseur 10 mm SCORE® mobile bearing insert – Size 3 - Thickness 10 mm	ET106-002 ET106-003
1-0200623	Insert mobile SCORE® – Taille 3 - Epaisseur 12 mm SCORE® mobile bearing insert – Size 3 - Thickness 12 mm	ET106-002 ET106-003
1-0200633	Insert mobile SCORE® – Taille 3 - Epaisseur 14 mm SCORE® mobile bearing insert – Size 3 - Thickness 14 mm	ET106-002 ET106-003
1-0200643	Insert mobile SCORE® – Taille 3 - Epaisseur 16 mm SCORE® mobile bearing insert – Size 3 - Thickness 16 mm	ET106-002 ET106-003
1-0200653	Insert mobile SCORE® – Taille 3 - Epaisseur 20 mm SCORE® mobile bearing insert – Size 3 - Thickness 20 mm	ET106-002 ET106-003
1-0200614	Insert mobile SCORE® – Taille 4 - Epaisseur 10 mm SCORE® mobile bearing insert – Size 4 - Thickness 10 mm	ET106-002 ET106-003
1-0200624	Insert mobile SCORE® – Taille 4 - Epaisseur 12 mm SCORE® mobile bearing insert – Size 4 - Thickness 12 mm	ET106-002 ET106-003
1-0200634	Insert mobile SCORE® – Taille 4 - Epaisseur 14 mm SCORE® mobile bearing insert – Size 4 - Thickness 14 mm	ET106-002 ET106-003
1-0200644	Insert mobile SCORE® – Taille 4 - Epaisseur 16 mm SCORE® mobile bearing insert – Size 4 - Thickness 16 mm	ET106-002 ET106-003
1-0200654	Insert mobile SCORE® – Taille 4 - Epaisseur 20 mm SCORE® mobile bearing insert – Size 4 - Thickness 20 mm	ET106-002 ET106-003
1-0200615	Insert mobile SCORE® – Taille 5 - Epaisseur 10 mm SCORE® mobile bearing insert – Size 5 - Thickness 10 mm	ET106-002 ET106-003
1-0200625	Insert mobile SCORE® – Taille 5 - Epaisseur 12 mm SCORE® mobile bearing insert – Size 5 - Thickness 12 mm	ET106-002 ET106-003
1-0200635	Insert mobile SCORE® – Taille 5 - Epaisseur 14 mm SCORE® mobile bearing insert – Size 5 - Thickness 14 mm	ET106-002 ET106-003

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Référence Reference	Désignation Designation	Etude Study
1-0200645	Insert mobile SCORE® – Taille 5 - Epaisseur 16 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 16 mm</i>	ET106-002 ET106-003
1-0200655	Insert mobile SCORE® – Taille 5 - Epaisseur 20 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 20 mm</i>	ET106-002 ET106-003
1-0200616	Insert mobile SCORE® – Taille 6 - Epaisseur 10 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 10 mm</i>	ET106-002 ET106-003
1-0200626	Insert mobile SCORE® – Taille 6 - Epaisseur 12 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 12 mm</i>	ET106-002 ET106-003
1-0200636	Insert mobile SCORE® – Taille 6 - Epaisseur 14 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 14 mm</i>	ET106-002 ET106-003
1-0200646	Insert mobile SCORE® – Taille 6 - Epaisseur 16 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 16 mm</i>	ET106-002 ET106-003
1-0200656	Insert mobile SCORE® – Taille 6 - Epaisseur 20 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 20 mm</i>	ET106-002 ET106-003
1-0200617	Insert mobile SCORE® – Taille 7 - Epaisseur 10 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 10 mm</i>	ET106-002 ET106-003
1-0200627	Insert mobile SCORE® – Taille 7 - Epaisseur 12 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 12 mm</i>	ET106-002 ET106-003
1-0200637	Insert mobile SCORE® – Taille 7 - Epaisseur 14 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 14 mm</i>	ET106-002 ET106-003
1-0200647	Insert mobile SCORE® – Taille 7 - Epaisseur 16 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 16 mm</i>	ET106-002 ET106-003
1-0200657	Insert mobile SCORE® – Taille 7 - Epaisseur 20 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 20 mm</i>	ET106-002 ET106-003

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - à cimenter

SCORE® Allergy Solution femoral component PCL sacrificing - Cemented

Référence Reference	Désignation Designation	Etude Study
1-0206101	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 1 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 1 RIGHT</i>	ET106-003
1-0206102	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 2 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 2 RIGHT</i>	ET106-003
1-0206103	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 3 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 3 RIGHT</i>	ET106-003
1-0206104	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 4 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 4 RIGHT</i>	ET106-003
1-0206105	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 5 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 5 RIGHT</i>	ET106-003
1-0206106	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 6 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 6 RIGHT</i>	ET106-003
1-0206107	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 7 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 7 RIGHT</i>	ET106-003
1-0206111	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 1 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 1 LEFT</i>	ET106-003
1-0206112	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 2 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 2 LEFT</i>	ET106-003
1-0206113	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 3 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 3 LEFT</i>	ET106-003
1-0206114	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 4 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 4 LEFT</i>	ET106-003
1-0206115	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 5 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 5 LEFT</i>	ET106-003
1-0206116	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 6 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 6 LEFT</i>	ET106-003
1-0206117	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 7 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 7 LEFT</i>	ET106-003

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter
SCORE® Allergy Solution tibial baseplate for mobile bearing insert - Cemented

Référence Reference	Désignation Designation	Etude Study
1-0206201	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 1 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 1</i>	ET106-003
1-0206202	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 2 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 2</i>	ET106-003
1-0206203	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 3 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 3</i>	ET106-003
1-0206204	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 4 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 4</i>	ET106-003
1-0206205	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 5 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 5</i>	ET106-003
1-0206206	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 6 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 6</i>	ET106-003
1-0206207	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 7 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 7</i>	ET106-003

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

SCORE® II Composant Fémoral - A Cimentier

SCORE® II Femoral Component - Cemented

Référence Reference	Désignation Designation	Etude Study
1-0205200	SCORE® II Composant Fémoral - A Cimentier - Taille 0 Droite <i>SCORE® II Femoral Component - Cemented - Size 0 Right</i>	ET106-001
1-0205201	SCORE® II Composant Fémoral - A Cimentier - Taille 1 Droite <i>SCORE® II Femoral Component - Cemented - Size 1 Right</i>	ET106-001
1-0205202	SCORE® II Composant Fémoral - A Cimentier - Taille 2 Droite <i>SCORE® II Femoral Component - Cemented - Size 2 Right</i>	ET106-001
1-0205203	SCORE® II Composant Fémoral - A Cimentier - Taille 3 Droite <i>SCORE® II Femoral Component - Cemented - Size 3 Right</i>	ET106-001
1-0205204	SCORE® II Composant Fémoral - A Cimentier - Taille 4 Droite <i>SCORE® II Femoral Component - Cemented - Size 4 Right</i>	ET106-001
1-0205205	SCORE® II Composant Fémoral - A Cimentier - Taille 5 Droite <i>SCORE® II Femoral Component - Cemented - Size 5 Right</i>	ET106-001
1-0205206	SCORE® II Composant Fémoral - A Cimentier - Taille 6 Droite <i>SCORE® II Femoral Component - Cemented - Size 6 Right</i>	ET106-001
1-0205207	SCORE® II Composant Fémoral - A Cimentier - Taille 7 Droite <i>SCORE® II Femoral Component - Cemented - Size 7 Right</i>	ET106-001
1-0205208	SCORE® II Composant Fémoral - A Cimentier - Taille 8 Droite <i>SCORE® II Femoral Component - Cemented - Size 8 Right</i>	ET106-001
1-0205300	SCORE® II Composant Fémoral - A Cimentier - Taille 0 Gauche <i>SCORE® II Femoral Component - Cemented - Size 0 Left</i>	ET106-001
1-0205301	SCORE® II Composant Fémoral - A Cimentier - Taille 1 Gauche <i>SCORE® II Femoral Component - Cemented - Size 1 Left</i>	ET106-001
1-0205302	SCORE® II Composant Fémoral - A Cimentier - Taille 2 Gauche <i>SCORE® II Femoral Component - Cemented - Size 2 Left</i>	ET106-001
1-0205303	SCORE® II Composant Fémoral - A Cimentier - Taille 3 Gauche <i>SCORE® II Femoral Component - Cemented - Size 3 Left</i>	ET106-001
1-0205304	SCORE® II Composant Fémoral - A Cimentier - Taille 4 Gauche <i>SCORE® II Femoral Component - Cemented - Size 4 Left</i>	ET106-001
1-0205305	SCORE® II Composant Fémoral - A Cimentier - Taille 5 Gauche <i>SCORE® II Femoral Component - Cemented - Size 5 Left</i>	ET106-001
1-0205306	SCORE® II Composant Fémoral - A Cimentier - Taille 6 Gauche <i>SCORE® II Femoral Component - Cemented - Size 6 Left</i>	ET106-001
1-0205307	SCORE® II Composant Fémoral - A Cimentier - Taille 7 Gauche <i>SCORE® II Femoral Component - Cemented - Size 7 Left</i>	ET106-001
1-0205308	SCORE® II Composant Fémoral - A Cimentier - Taille 8 Gauche <i>SCORE® II Femoral Component - Cemented - Size 8 Left</i>	ET106-001

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

SCORE® II Composant fémoral Sans ciment HAP

SCORE® II Femoral Component HA Coated Cementless

Référence Reference	Désignation Designation	Etude Study
1-0205400	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 0 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 0 Right</i>	ET106-001
1-0205401	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 1 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 1 Right</i>	ET106-001
1-0205402	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 2 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 2 Right</i>	ET106-001
1-0205403	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 3 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 3 Right</i>	ET106-001
1-0205404	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 4 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 4 Right</i>	ET106-001
1-0205405	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 5 Droite <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 5 Right</i>	ET106-001
1-0205406	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 6 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 6 Right</i>	ET106-001
1-0205407	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 7 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 7 Right</i>	ET106-001
1-0205408	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 8 Droite <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 8 Right</i>	ET106-001
1-0205500	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 0 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 0 Left</i>	ET106-001
1-0205501	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 1 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 1 Left</i>	ET106-001
1-0205502	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 2 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 2 Left</i>	ET106-001
1-0205503	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 3 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 3 Left</i>	ET106-001
1-0205504	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 4 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 4 Left</i>	ET106-001
1-0205505	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 5 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 5 Left</i>	ET106-001
1-0205506	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 6 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 6 Left</i>	ET106-001
1-0205507	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 7 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 7 Left</i>	ET106-001
1-0205508	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 8 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 8 Left</i>	ET106-001

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

SCORE® II Insert tibial mobile

SCORE® II Mobile Bearing Insert

Référence Reference	Désignation Designation	Etude Study
1-0205610	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 10 mm</i>	ET106-001
1-0205660	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 11 mm</i>	ET106-001
1-0205620	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 12 mm</i>	ET106-001
1-0205630	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 14 mm</i>	ET106-001
1-0205640	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 16 mm</i>	ET106-001
1-0205650	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 20 mm</i>	ET106-001
1-0205611	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 10 mm</i>	ET106-001
1-0205661	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 11 mm</i>	ET106-001
1-0205621	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 12 mm</i>	ET106-001
1-0205631	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 14 mm</i>	ET106-001
1-0205641	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 16 mm</i>	ET106-001
1-0205651	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 20 mm</i>	ET106-001
1-0205612	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 10 mm</i>	ET106-001
1-0205662	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 11 mm</i>	ET106-001
1-0205622	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 12 mm</i>	ET106-001
1-0205632	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 14 mm</i>	ET106-001
1-0205642	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 16 mm</i>	ET106-001
1-0205652	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 20 mm</i>	ET106-001
1-0205613	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 10 mm</i>	ET106-001
1-0205663	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 11 mm</i>	ET106-001
1-0205623	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 12 mm</i>	ET106-001
1-0205633	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 14 mm</i>	ET106-001
1-0205643	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 16 mm</i>	ET106-001
1-0205653	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 20 mm</i>	ET106-001
1-0205614	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 10 mm</i>	ET106-001
1-0205664	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 11 mm</i>	ET106-001
1-0205624	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 12 mm</i>	ET106-001
1-0205634	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 14 mm</i>	ET106-001
1-0205644	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 16 mm</i>	ET106-001
1-0205654	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 20 mm</i>	ET106-001

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET106

Date de mise à jour / Updated on :
2019-MAR-29

Référence Reference	Désignation Designation	Etude Study
1-0205615	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 10 mm</i>	ET106-001
1-0205665	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 11 mm</i>	ET106-001
1-0205625	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 12 mm</i>	ET106-001
1-0205635	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 14 mm</i>	ET106-001
1-0205645	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 16 mm</i>	ET106-001
1-0205655	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 20 mm</i>	ET106-001
1-0205616	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 10 mm</i>	ET106-001
1-0205666	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 11 mm</i>	ET106-001
1-0205626	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 12 mm</i>	ET106-001
1-0205636	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 14 mm</i>	ET106-001
1-0205646	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 16 mm</i>	ET106-001
1-0205656	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 20 mm</i>	ET106-001
1-0205617	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 10 mm</i>	ET106-001
1-0205667	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 11 mm</i>	ET106-001
1-0205627	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 12 mm</i>	ET106-001
1-0205637	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 14 mm</i>	ET106-001
1-0205647	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 16 mm</i>	ET106-001
1-0205657	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 20 mm</i>	ET106-001
1-0205618	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 10 mm</i>	ET106-001
1-0205668	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 11 mm</i>	ET106-001
1-0205628	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 12 mm</i>	ET106-001
1-0205638	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 14 mm</i>	ET106-001
1-0205648	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 16 mm</i>	ET106-001
1-0205658	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 20 mm</i>	ET106-001

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Date de mise à jour / Updated on :

2019-MAR-29

Dossier / File :
ET106

Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter

Allergy Solution extension stem for Total Knee Prosthesis – Cemented

Référence Reference	Désignation Designation	Etude Study
1-0207310	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø10 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø10 Lg 75 mm</i>	106-003
1-0207311	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø10 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø10 Lg 100 mm</i>	106-003
1-0207312	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø10 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø10 Lg 150 mm</i>	106-003
1-0207320	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø12 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø12 Lg 75 mm</i>	106-003
1-0207321	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø12 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø12 Lg 100 mm</i>	106-003
1-0207322	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø12 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø12 Lg 150 mm</i>	106-003
1-0207323	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø12 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø12 Lg 200 mm</i>	106-003
1-0207330	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø14 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø14 Lg 75 mm</i>	106-003
1-0207331	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø14 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø14 Lg 100 mm</i>	106-003
1-0207332	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø14 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø14 Lg 150 mm</i>	106-003
1-0207333	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø14 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø14 Lg 200 mm</i>	106-003
1-0207341	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø16 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø16 Lg 100 mm</i>	106-003
1-0207342	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø16 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø16 Lg 150 mm</i>	106-003
1-0207343	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter - Ø16 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented - Ø16 Lg 200 mm</i>	106-003



By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 615308

Issued To:

AMPLITUDE

11 Cours Jacques OFFENBACH

ZA Mozart 2

VALENCE

26000

France

In respect of:

Design, development and manufacture of: hip joint replacement and hemi-hip arthroplasty devices, knee joint replacement devices, osteosynthesis implants, and associated trial prostheses, instruments connecting to active devices and accessories; Computer assisted surgery systems.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-04-27**

Date: **2021-05-12**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Bay Building, John M. Keynesplein 9, 1056 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
Date: **2021-05-12**
Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:**Service(s) supplied**

ACNIS INTERNATIONAL
17 Rue des Frères Lumière
Chassieu
69680
France

Crucial Supplier

ATS SAS
ZI de Bruèges
Avenue Monge
BP 80286
Ales Cedex
30106
France

Crucial Supplier
Manufacture

CeramTec GmbH
Medical Products Division
CeramTec Platz 1-9
73207 Plochingen
Germany

Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
CeramTec GmbH Medical Products Division CeramTec-Weg 1 95615 Marktredwitz Germany	Manufacture
CF Plastiques ZAC des Bruyères 43, rue des Bruyères Pusignan 69330 France	Assembly Manufacture Other Critical Processes Packaging
Charles PERY & Cie s.a.s. 360, Avenue du Stade B.P. 27 Scionzier CEDEX 74951 France	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
DOT GmbH Charles Darwin Ring 3b 18059 Rostock Germany	Other Critical Processes
ECP SAS 395 rue Louis Lépine 34000 Montpellier France	Assembly Other Critical Processes Packaging
Ets Marle SAS BP 46, ZI rue Lavoisier Nogent 52800 France	Crucial Supplier Manufacture
Firm Industrie ZA Blacheronde d'Etoile Etoile Sur Rhone 26800 France	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
HTI TECHNOLOGIES 49, Avenue Franklin Roosevelt DECINES 69150 France	Other Critical Processes
Invibio Ltd. Invibio Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom	Crucial Supplier
IONISOS SAS Parc Dombes Côtière Activités 01120 Dagneux France	Radiation (Gamma Sterilization)

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
Lincotek Trento S.p.A. Loc. Ciré- Via Al Dos de la Roda, 60 38057 Pergine Valsugana (TN) Italy	Manufacture Other Critical Processes
Marle Finishing SAS 443, rue René Cassin La Talaudière 42350 France	Manufacture Other Critical Processes Packaging Surface Treatment
MediTECH Medical Polymers Division of Mitsubishi Chemical Advance Materials Inc, 2710 American Way Ft. Wayne Indiana 46809 USA	Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
Microweld Parc Altais, Rue Uranus CHAVANOD 74650 France	Other Critical Processes
Orchid Orthopedic Solutions Memphis Location 4600 E. Shelby Drive, Suite 1 Memphis Tennessee 38118 USA	Surface Treatment
Orchid Orthopedic Solutions dba Orchid Lansing 1489 Cedar St. Holt Michigan 48842 USA	Crucial Supplier Manufacture Other Critical Processes

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
Orchid Orthopedic Solutions LLC 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	Other Critical Processes
Poli Alpes 12, rue Laurent de Lavoisier Portes Les Valence 26800 France	Surface Treatment
Poli-Tech' ZA Blacheronde d'Etoile Etoile Sur Rhone 26800 France	Surface Treatment

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
Date: **2021-05-12**
Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:**Service(s) supplied**

SAS BELMONTE
Chemin du Pan
ZAC des Couleures
Valence
26000
France

Manufacture

Serret Mecanique
185 Allee De L'Hermitage - Zone
Industrielle SUD
Bourg De Peage
26300
France

Crucial Supplier

SIMAGEC s.a.s.
54 Avenue de la Plaine
Zone Industrielle
13106 Rousset Cedex
France

Assembly
Other Critical Processes
Packaging

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
Societe Mecanique Pansu Quartier de Brezide Beaumont Les Valence 26760 France	Crucial Supplier
STAINLESS 4 rue Thalès Dannemarie-sur-Crete 25410 France	Crucial Supplier
Sterlab 2720 Chemin Saint Bernard Vallauris 06224 France	ETO Sterilization

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:

Service(s) supplied

Synergy Health Marseille - Groupe Steris
 Site De Marseille
 Min 712 - Les Arnavaux
 Marseille Cedex 14
 13323
 France

Radiation (Gamma Sterilization)

UDT Meca
 ZI Les Auréas
 5 allée Bernard Palissy
 Valence
 26000
 France

Crucial Supplier

VIT RESSORT
 ZA le Boutariq
 Rue du Pic de Bure
 Veynes
 05400
 France

Crucial Supplier

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:

WESTLAKE PLASTICS EUROPE
 2 rue de Maëstricht
 TOURCOING
 59200
 France

Service(s) supplied

Crucial Supplier

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 615308**
Date: **2021-05-12**
Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Date	Reference number	Action
27 April 2015	8165223	First Issue - Transfer from another Notified Body
08 July 2015	8291732	Extension to scope to include the Trial Prostheses Class IIa devices
09 May 2017	8712742	Certificate Renewal Clarification of scope Addition of significant subcontractors and crucial suppliers: HTI Technologies, MedITECH Medical Polymers (Division of Quadrant EPP), Microweld, Progress Silicones, Stainless and Westlake Plastic Europe SAS Removal of significant subcontractors: MEDICAL Group CORP, MEDIMET and QUADRANT
15 March 2018	8906823	Addition of significant subcontractors and crucial suppliers: Poli-Tech', Belmonte, Firm Industrie, Marle Finishing SAS (22 Rue de la Mollanche & 443 Rue René Cassin), Poli Alpes, UDT Meca, Societe Mecanique Pansu, Serret Mecanique and S.A.R.L. Devise. Address changes to VIT RESSORT from 'Chemin de Vignes, Veynes, 05400, France' to 'ZA le Boutariq, Rue du Pic de Bure, 05400 Veynes, France' and to CeramTech from 'Fabrikstrasse 23-29, Plochingen, 73207, Germany' to 'CeramTec GmbH, Medical Products Division, CeramTec Platz 1-9, 73207 Plochingen, Germany'
05 March 2019	8432821	Traceable to NB0086.

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Date	Reference number	Action
03 July 2020	9653997	Addition of alternative gamma sterilisation provider: IONISOS Dagneux
Current	3059440	Certificate Renewal Review and approval for compliance with Regulation 207/2012 Addition of critical subcontractors CeramTec GmbH, Marktredwitz location, for manufacture activities; CF Plastiques for manufacture, assembly, other critical processes and packaging activities; Charles PERY for manufacture activities; Orchid orthopedic Solution dba Orchid Lansing for crucial supplier, other critical processes and manufacture activities; Orchid orthopedic Solutions, Memphis location, for surface treatment activities; Orchid Orthopedic Solutions LLC for other critical processes; STERLAB for ETO Sterilization activities. Addition of Surface Treatment to services provided by MARLE FINISHING SAS – LA Talaudière site Address changes to ACNIS INTERNATIONAL from '220 Rue Léon Blum 69100 VILLEURBANNE, France' to '17 rue des Frères Lumière 69680 CHASSIEU, France', DOT GmbH from 'Charles Darwin Ring 1 a, 18059 Rostock, GERMANY' to 'Charles Darwin Ring 3b, 18059 Rostock, GERMANY' Minor address changes to SAS BELMONTE from Chemin du Pau to Chemin du Pan, MARLE FINISHING SAS – La Talaudière site from

...making excellence a habit.™

Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 615308**
 Date: **2021-05-12**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Date	Reference number	Action
		rené Cassin to René Cassin and Synergy Health Marseille from 13323 MARSEILLE to 13323 MARSEILLE Cedex 14 Change names from CeramTec to CeramTec GmbH, from ENTEGRIS to ECP SAS, from MARLE SAS to ETS MARLE SAS, from EUROCOATING to LINCOTEK TRENTO SPA, from MediTECH Medical Polymers, Division of Quandrant EPP to MediTECH Medical Polymers, Division of Mitsubishi Chemical Advanced Materials Inc; from SIMAGEC to SIMAGEC s.a.s.; from Synergy Health Marseille to Synergy Health Marseille – Groupe Steris Site de Marseille; from Westlake Plastics Europe SAS to Westlake Plastics Europe. Removal of critical subcontractor MARLE FINISHING – Sorbiers site for Manufacture and Other Critical Processes Removal of crucial suppliers PROGRESS SILICONES, SARL DEVISE and SERRE G. MECANIQUE

...making excellence a habit.™

Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.



By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.

CE 615311

Issued To:

AMPLITUDE

11 Cours Jacques OFFENBACH

ZA Mozart 2

VALENCE

26000

France

In respect of:

SCORE® and SCORE® II Primary Total Knee Prostheses

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® femoral component PCL sacrificing – Cemented
Material: Chrome Cobalt (CrCo) complying with ISO 5832-4

Référence Reference	Désignation Designation
1-0200201	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 1 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 1 RIGHT</i>
1-0200202	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 2 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 2 RIGHT</i>
1-0200203	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 3 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 3 RIGHT</i>
1-0200204	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 4 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 4 RIGHT</i>
1-0200205	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 5 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 5 RIGHT</i>
1-0200206	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 6 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 6 RIGHT</i>
1-0200207	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 7 DROITE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 7 RIGHT</i>
1-0200211	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 1 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 1 LEFT</i>
1-0200212	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 2 GAUCHE <i>SCORE® Femoral component PCL sacrificing – Cemented – Size 2 LEFT</i>
1-0200213	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 3 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 3 LEFT</i>
1-0200214	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 4 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 4 LEFT</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0200215	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 5 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 5 LEFT</i>
1-0200216	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 6 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 6 LEFT</i>
1-0200217	Condyle fémoral SCORE® sans conservation du LCP - A cimenter – Taille 7 GAUCHE <i>SCORE® femoral component PCL sacrificing – Cemented – Size 7 LEFT</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 3 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® femoral component PCL sacrificing – HA coated – Cementless

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4

Coating: Titanium spray and Hydroxyapatite (Ti + HA) complying with ASTM F1580 and ASTM F1185

Référence Reference	Désignation Designation
1-0200101	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 1 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 1 RIGHT</i>
1-0200102	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 2 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 2 RIGHT</i>
1-0200103	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 3 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 3 RIGHT</i>
1-0200104	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 4 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 4 RIGHT</i>
1-0200105	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 5 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 5 RIGHT</i>
1-0200106	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 6 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 6 RIGHT</i>
1-0200107	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 7 DROITE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 7 RIGHT</i>
1-0200111	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 1 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 1 LEFT</i>
1-0200112	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 2 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 2 LEFT</i>
1-0200113	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 3 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 3 LEFT</i>
1-0200114	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 4 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 4 LEFT</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 4 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0200115	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 5 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 5 LEFT</i>
1-0200116	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 6 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 6 LEFT</i>
1-0200117	Condyle fémoral SCORE® sans conservation du LCP - HAP - sans ciment – Taille 7 GAUCHE <i>SCORE® femoral component PCL sacrificing – HA coated - Cementless – Size 7 LEFT</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 5 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264294.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® Allergy Solution femoral component PCL sacrificing - Cemented
Material: Chrome Cobalt (CrCo) complying with ISO 5832-4
Coating: Titanium nitride (TiN)

Référence Reference	Désignation Designation
1-0206101	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 1 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 1 RIGHT</i>
1-0206102	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 2 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 2 RIGHT</i>
1-0206103	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 3 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 3 RIGHT</i>
1-0206104	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 4 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 4 RIGHT</i>
1-0206105	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 5 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 5 RIGHT</i>
1-0206106	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 6 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 6 RIGHT</i>
1-0206107	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 7 DROITE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 7 RIGHT</i>
1-0206111	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 1 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 1 LEFT</i>
1-0206112	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 2 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 2 LEFT</i>
1-0206113	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 3 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 3 LEFT</i>
1-0206114	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 4 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 4 LEFT</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 6 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0206115	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 5 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 5 LEFT</i>
1-0206116	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 6 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 6 LEFT</i>
1-0206117	Condyle fémoral SCORE® Allergie Solution sans conservation du LCP - A cimenter - Taille 7 GAUCHE <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented - Size 7 LEFT</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 7 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® tibial base plate for mobile bearing insert – Cemented

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4, and stainless steel (M30NW) complying with ISO 5832-9

Référence Reference	Désignation Designation
1-0200501	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 1 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 1</i>
1-0200502	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 2 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 2</i>
1-0200503	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 3 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 3</i>
1-0200504	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 4 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 4</i>
1-0200505	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 5 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 5</i>
1-0200506	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 6 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 6</i>
1-0200507	Embase tibiale SCORE® pour insert mobile - A cimenter – Taille 7 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 7</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 8 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® tibial base plate for mobile bearing insert – HA coated - cementless

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4, and stainless steel (M30NW) complying with ISO 5832-9

Coating: Titanium spray and Hydroxyapatite (Ti + HA) complying with ASTM F1580 and ASTM F1185

Référence Reference	Désignation Designation
1-0200401	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 1 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 1</i>
1-0200402	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 2 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 2</i>
1-0200403	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 3 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 3</i>
1-0200404	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 4 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 4</i>
1-0200405	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 5 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 5</i>
1-0200406	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 6 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 6</i>
1-0200407	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 7 <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless – Size 7</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 9 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® Allergy Solution tibial baseplate for mobile bearing insert - Cemented
Material: Chrome Cobalt (CrCo) complying with ISO 5832-4, and stainless steel (M30NW) complying with ISO 5832-9
Coating: Titanium nitride (TiN)

Référence Reference	Désignation Designation
1-0206201	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 1 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 1</i>
1-0206202	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 2 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 2</i>
1-0206203	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 3 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 3</i>
1-0206204	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 4 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 4</i>
1-0206205	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 5 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 5</i>
1-0206206	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 6 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 6</i>
1-0206207	Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter – Taille 7 <i>SCORE® Allergy Solution tibial base plate for mobile bearing insert - Cemented – Size 7</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 10 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® mobile bearing insert

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0200611	Insert mobile SCORE® – Taille 1 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 1 - Thickness 10 mm</i>
1-0200621	Insert mobile SCORE® – Taille 1 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 1 - Thickness 12 mm</i>
1-0200631	Insert mobile SCORE® – Taille 1 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 1 - Thickness 14 mm</i>
1-0200641	Insert mobile SCORE® – Taille 1 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 1 - Thickness 16 mm</i>
1-0200651	Insert mobile SCORE® – Taille 1 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 1 - Thickness 20 mm</i>
1-0200612	Insert mobile SCORE® – Taille 2 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 2 - Thickness 10 mm</i>
1-0200622	Insert mobile SCORE® – Taille 2 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 2 - Thickness 12 mm</i>
1-0200632	Insert mobile SCORE® – Taille 2 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 2 - Thickness 14 mm</i>
1-0200642	Insert mobile SCORE® – Taille 2 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 2 - Thickness 16 mm</i>
1-0200652	Insert mobile SCORE® – Taille 2 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 2 - Thickness 20 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 11 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0200613	Insert mobile SCORE® – Taille 3 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 3 - Thickness 10 mm</i>
1-0200623	Insert mobile SCORE® – Taille 3 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 3 - Thickness 12 mm</i>
1-0200633	Insert mobile SCORE® – Taille 3 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 3 - Thickness 14 mm</i>
1-0200643	Insert mobile SCORE® – Taille 3 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 3 - Thickness 16 mm</i>
1-0200653	Insert mobile SCORE® – Taille 3 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 3 - Thickness 20 mm</i>
1-0200614	Insert mobile SCORE® – Taille 4 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 4 - Thickness 10 mm</i>
1-0200624	Insert mobile SCORE® – Taille 4 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 4 - Thickness 12 mm</i>
1-0200634	Insert mobile SCORE® – Taille 4 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 4 - Thickness 14 mm</i>
1-0200644	Insert mobile SCORE® – Taille 4 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 4 - Thickness 16 mm</i>
1-0200654	Insert mobile SCORE® – Taille 4 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 4 - Thickness 20 mm</i>
1-0200615	Insert mobile SCORE® – Taille 5 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 10 mm</i>
1-0200625	Insert mobile SCORE® – Taille 5 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 12 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 12 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0200635	Insert mobile SCORE® – Taille 5 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 14 mm</i>
1-0200645	Insert mobile SCORE® – Taille 5 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 16 mm</i>
1-0200655	Insert mobile SCORE® – Taille 5 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 5 - Thickness 20 mm</i>
1-0200616	Insert mobile SCORE® – Taille 6 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 10 mm</i>
1-0200626	Insert mobile SCORE® – Taille 6 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 12 mm</i>
1-0200636	Insert mobile SCORE® – Taille 6 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 14 mm</i>
1-0200646	Insert mobile SCORE® – Taille 6 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 16 mm</i>
1-0200656	Insert mobile SCORE® – Taille 6 - Épaisseur 20 mm <i>SCORE® mobile bearing insert – Size 6 - Thickness 20 mm</i>
1-0200617	Insert mobile SCORE® – Taille 7 - Épaisseur 10 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 10 mm</i>
1-0200627	Insert mobile SCORE® – Taille 7 - Épaisseur 12 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 12 mm</i>
1-0200637	Insert mobile SCORE® – Taille 7 - Épaisseur 14 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 14 mm</i>
1-0200647	Insert mobile SCORE® – Taille 7 - Épaisseur 16 mm <i>SCORE® mobile bearing insert – Size 7 - Thickness 16 mm</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 13 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0200657	Insert mobile SCORE® – Taille 7 - Épaisseur 20 mm SCORE® mobile bearing insert – Size 7 - Thickness 20 mm

SCORE® II Femoral Component – Cemented

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4

Référence Reference	Désignation Designation
1-0205200	SCORE® II Composant Fémoral - A Ciment - Taille 0 Droite SCORE® II Femoral Component - Cemented - Size 0 Right
1-0205201	SCORE® II Composant Fémoral - A Ciment - Taille 1 Droite SCORE® II Femoral Component - Cemented - Size 1 Right
1-0205202	SCORE® II Composant Fémoral - A Ciment - Taille 2 Droite SCORE® II Femoral Component - Cemented - Size 2 Right
1-0205203	SCORE® II Composant Fémoral - A Ciment - Taille 3 Droite SCORE® II Femoral Component - Cemented - Size 3 Right
1-0205204	SCORE® II Composant Fémoral - A Ciment - Taille 4 Droite SCORE® II Femoral Component - Cemented - Size 4 Right
1-0205205	SCORE® II Composant Fémoral - A Ciment - Taille 5 Droite SCORE® II Femoral Component - Cemented - Size 5 Right
1-0205206	SCORE® II Composant Fémoral - A Ciment - Taille 6 Droite SCORE® II Femoral Component - Cemented - Size 6 Right
1-0205207	SCORE® II Composant Fémoral - A Ciment - Taille 7 Droite SCORE® II Femoral Component - Cemented - Size 7 Right

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 14 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205208	SCORE® II Composant Fémoral - A Cimentier - Taille 8 Droite <i>SCORE® II Femoral Component - Cemented - Size 8 Right</i>
1-0205300	SCORE® II Composant Fémoral - A Cimentier - Taille 0 Gauche <i>SCORE® II Femoral Component - Cemented - Size 0 Left</i>
1-0205301	SCORE® II Composant Fémoral - A Cimentier - Taille 1 Gauche <i>SCORE® II Femoral Component - Cemented - Size 1 Left</i>
1-0205302	SCORE® II Composant Fémoral - A Cimentier - Taille 2 Gauche <i>SCORE® II Femoral Component - Cemented - Size 2 Left</i>
1-0205303	SCORE® II Composant Fémoral - A Cimentier - Taille 3 Gauche <i>SCORE® II Femoral Component - Cemented - Size 3 Left</i>
1-0205304	SCORE® II Composant Fémoral - A Cimentier - Taille 4 Gauche <i>SCORE® II Femoral Component - Cemented - Size 4 Left</i>
1-0205305	SCORE® II Composant Fémoral - A Cimentier - Taille 5 Gauche <i>SCORE® II Femoral Component - Cemented - Size 5 Left</i>
1-0205306	SCORE® II Composant Fémoral - A Cimentier - Taille 6 Gauche <i>SCORE® II Femoral Component - Cemented - Size 6 Left</i>
1-0205307	SCORE® II Composant Fémoral - A Cimentier - Taille 7 Gauche <i>SCORE® II Femoral Component - Cemented - Size 7 Left</i>
1-0205308	SCORE® II Composant Fémoral - A Cimentier - Taille 8 Gauche <i>SCORE® II Femoral Component - Cemented - Size 8 Left</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 15 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® II Femoral Component HA Coated Cementless

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4

Coating: Titanium spray and hydroxyapatite (Ti + HA) complying with ASTM F1580 and ASTM F1185

Référence Reference	Désignation Designation
1-0205400	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 0 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 0 Right</i>
1-0205401	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 1 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 1 Right</i>
1-0205402	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 2 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 2 Right</i>
1-0205403	SCORE® II Composant fémoral – HAP - Sans ciment - Taille 3 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 3 Right</i>
1-0205404	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 4 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 4 Right</i>
1-0205405	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 5 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 5 Right</i>
1-0205406	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 6 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 6 Right</i>
1-0205407	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 7 Droite <i>SCORE® II Femoral Component - HA Coated – Cementless - Size 7 Right</i>
1-0205408	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 8 Droite <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 8 Right</i>
1-0205500	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 0 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless – Size 0 Left</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 16 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205501	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 1 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 1 Left</i>
1-0205502	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 2 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 2 Left</i>
1-0205503	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 3 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 3 Left</i>
1-0205504	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 4 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 4 Left</i>
1-0205505	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 5 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 5 Left</i>
1-0205506	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 6 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 6 Left</i>
1-0205507	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 7 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 7 Left</i>
1-0205508	SCORE® II Composant fémoral - HAP - Sans ciment - Taille 8 Gauche <i>SCORE® II Femoral Component - HA Coated - Cementless - Size 8 Left</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 17 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® II Mobile Bearing Insert

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0205610	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 10 mm</i>
1-0205660	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 11 mm</i>
1-0205620	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 12 mm</i>
1-0205630	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 14 mm</i>
1-0205640	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 16 mm</i>
1-0205650	SCORE® II Insert tibial mobile - Taille 0 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 0 Thickness 20 mm</i>
1-0205611	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 10 mm</i>
1-0205661	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 11 mm</i>
1-0205621	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 12 mm</i>
1-0205631	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 14 mm</i>
1-0205641	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 16 mm</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 18 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205651	SCORE® II Insert tibial mobile - Taille 1 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 1 Thickness 20 mm</i>
1-0205612	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 10mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 10 mm</i>
1-0205662	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 11 mm</i>
1-0205622	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 12 mm</i>
1-0205632	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 14 mm</i>
1-0205642	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 16 mm</i>
1-0205652	SCORE® II Insert tibial mobile - Taille 2 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 2 Thickness 20 mm</i>
1-0205613	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 10 mm</i>
1-0205663	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 11 mm</i>
1-0205623	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 12 mm</i>
1-0205633	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 14 mm</i>
1-0205643	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 16 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 19 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205653	SCORE® II Insert tibial mobile - Taille 3 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 3 Thickness 20 mm</i>
1-0205614	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 10 mm</i>
1-0205664	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 11 mm</i>
1-0205624	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 12 mm</i>
1-0205634	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 14 mm</i>
1-0205644	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 16 mm</i>
1-0205654	SCORE® II Insert tibial mobile - Taille 4 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 4 Thickness 20 mm</i>
1-0205615	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 10 mm</i>
1-0205665	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 11 mm</i>
1-0205625	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 12 mm</i>
1-0205635	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 14 mm</i>
1-0205645	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 16 mm</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 20 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205655	SCORE® II Insert tibial mobile - Taille 5 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 5 Thickness 20 mm</i>
1-0205616	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 10 mm</i>
1-0205666	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 11 mm</i>
1-0205626	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 12 mm</i>
1-0205636	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 14 mm</i>
1-0205646	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 16 mm</i>
1-0205656	SCORE® II Insert tibial mobile - Taille 6 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 6 Thickness 20 mm</i>
1-0205617	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 10 mm</i>
1-0205667	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 11 mm</i>
1-0205627	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 12 mm</i>
1-0205637	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 14 mm</i>
1-0205647	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 16 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 21 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0205657	SCORE® II Insert tibial mobile - Taille 7 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 7 Thickness 20 mm</i>
1-0205618	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 10 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 10 mm</i>
1-0205668	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 11 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 11 mm</i>
1-0205628	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 12 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 12 mm</i>
1-0205638	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 14 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 14 mm</i>
1-0205648	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 16 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 16 mm</i>
1-0205658	SCORE® II Insert tibial mobile - Taille 8 Épaisseur 20 mm <i>SCORE® II Mobile Bearing Insert – Size 8 Thickness 20 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 22 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

SCORE® tibial base plate for mobile bearing insert - HA coated – cementless

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4 and stainless steel (M30NW) complying with ISO 5832-9

Coating: Titanium spray and hydroxyapatite (Ti + HA) complying with ASTM F1580 and ASTM F1185

Référence Reference	Désignation Designation
1-0200400	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 0 <i>SCORE® tibial base plate for mobile bearing insert - HA coated - cementless – Size 0</i>
1-0200408	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 8 <i>SCORE® tibial base plate for mobile bearing insert - HA coated - cementless – Size 8</i>

SCORE® tibial base plate for mobile bearing insert – Cemented

Material: Chrome Cobalt (CrCo) complying with ISO 5832-4 and stainless steel (M30NW) complying with ISO 5832-9

Référence Reference	Désignation Designation
1-0200500	Embase tibiale SCORE® pour insert mobile - A cimenter - Taille 0 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 0</i>
1-0200508	Embase tibiale SCORE® pour insert mobile - A cimenter - Taille 8 <i>SCORE® tibial base plate for mobile bearing insert – Cemented – Size 8</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 23 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Allergy Solution extension stem for Total Knee Prosthesis – Cemented

Material: Stainless steel (M30NW) complying with ISO 5832-9

Coating: Titanium nitride

Référence Reference	Désignation Designation
1-0207310	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø10 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø10 Lg 75 mm</i>
1-0207311	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø10 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø10 Lg 100 mm</i>
1-0207312	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø10 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø10 Lg 150 mm</i>
1-0207320	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø12 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø12 Lg 75 mm</i>
1-0207321	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø12 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø12 Lg 100 mm</i>
1-0207322	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø12 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø12 Lg 150 mm</i>
1-0207323	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø12 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø12 Lg 200 mm</i>
1-0207330	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø14 Lg 75 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø14 Lg 75 mm</i>
1-0207331	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø14 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø14 Lg 100 mm</i>
1-0207332	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø14 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø14 Lg 150 mm</i>

First Issued: **2015-04-28**Date: **2020-10-16**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 24 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0207333	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø14 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø14 Lg 200 mm</i>
1-0207341	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø16 Lg 100 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø16 Lg 100 mm</i>
1-0207342	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø16 Lg 150 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø16 Lg 150 mm</i>
1-0207343	Quille longue Allergie Solution pour Prothèse Totale de Genou – A cimenter – Ø16 Lg 200 mm <i>Allergy Solution extension stem for Total Knee Prosthesis – Cemented – Ø16 Lg 200 mm</i>

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 25 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
 This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
 BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
 A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Certificate History

Date	Reference Number	Action
28 April 2015	10147063	First Issue. Transfer from another Notified Body.
23 January 2016	10159098	Change affecting Tyvek® 1073B packaging materials – all product codes are affected except patellae codes 1-020212x and 1-020092x (x = 3, 6, 9) and 1-020083x (x = 0, 3, 6, 9).
11 February 2016	10158773	Patella codes removed and transferred to CE 643576.
15 March 2018	8861055	Addition of SCORE II components to scope - Femoral Component Cemented (1-02052XX and 1-02053XX), Femoral Component HA Coated Cementless (1-02054XX and 1-02056XX) and Mobile Bearing Insert Size (1-02056XX). Addition of SCORE Tibial Base Plate HA Coated Cementless Sizes 0 and 8 (1-0200400 and 1-0200408) and SCORE Tibial Base Plate Cemented Sizes 0 and 8 (1-0200500 and 1-0200508). Change to IFU to now cover whole SCORE® product range.
05 July 2018	8847706	Change for the production transfer of the final packaging activity from the subcontractor EUROCOATING to AMPLITUDE, addition of an additional cleaning step, change of the labelling. Only HA coated references are concerned.
05 March 2019	8432821	Traceable to NB 0086.
03 October 2019	9689415	Certificate Renewal. Addition of Score Allergy Solution extension stems product codes (formerly under CE 615314).

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 26 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Date	Reference Number	Action
06 February 2020	9671566	Approval of new packaging configurations for the product SCORE® Primary Total Knee Prosthesis, product codes 1-0200101 to 1-0200107 and 1-0200111 to 1-0200117 (SC 1-02001 Packaging Specification), 1-0200201 to 1-0200207 and 1-0200211 to 1-0200217 (SC 1-02002 Packaging Specification) and SCORE® Allergy Solution Primary Total Knee Prosthesis, product codes 1-206101 to 1-206107 and 1-206111 to 1-206117 (SC 1-02061 Packaging Specification).
03 July 2020	9653997	Approval of addition of alternative gamma sterilisation provider (IONISOS Dagneux) and increase of maximum acceptable dose from 40.9kGy to 45kGy (at original and additional sterilisation sites). This change is applicable to the following devices: • SCORE® Femoral Component Cementless • SCORE® Tibial Baseplate Cementless • SCORE® II Femoral Component Cementless • SCORE® Femoral Component Cemented • SCORE® Tibial Baseplate Cemented • SCORE® II Femoral Component Cemented • SCORE® AS Femoral Component Cemented • SCORE® AS Tibial Baseplate Cemented

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 27 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 615311

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Date	Reference Number	Action
Current	9660163	Approval of new packaging configuration for the product SCORE® mobile bearing insert - Product code 1-02006XX and SCORE® II mobile bearing insert – product code 1-02056XX. Approval of AMPLITUDE 11 Cours Jacques Offenbach ZA Mozart 2 26000 Valence France as additional location for cleaning/packaging activities for the product SCORE® mobile bearing insert - Product code 1-02006XX and SCORE® II mobile bearing insert – product code 1-02056XX. Updated labelling on the above products to include MR conditional symbols.

First Issued: **2015-04-28**

Date: **2020-10-16**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 28 of 28

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

Référence Reference	Désignation Designation	Etude Study
1-0200501	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 1 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 1	ET106-002
1-0200502	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 2 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 2	ET106-002
1-0200503	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 3 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 3	ET106-002
1-0200504	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 4 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 4	ET106-002
1-0200505	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 5 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 5	ET106-002
1-0200506	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 6 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 6	ET106-002
1-0200507	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 7 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 7	ET106-002
1-0200500	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 0 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 0	ET106-001
1-0200508	Embase tibiale SCORE ^(®) pour insert mobile - A ciment - Taille 8 SCORE ^(®) tibial base plate for mobile bearing insert – Cemented – Size 8	ET106-001
1-0200401	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 1 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 1	ET106-002
1-0200402	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 2 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 2	ET106-002
1-0200403	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 3 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 3	ET106-002
1-0200404	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 4 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 4	ET106-002
1-0200405	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 5 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 5	ET106-002
1-0200406	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 6 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 6	ET106-002
1-0200407	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 7 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 7	ET106-002
1-0200400	Embase tibiale SCORE ^(®) pour insert mobile - HAP - sans ciment - Taille 0 SCORE ^(®) tibial base plate for mobile bearing insert – HA coated - cementless – Size 0	ET106-001

1-0200408	Embase tibiale SCORE® pour insert mobile - HAP - sans ciment – Taille 8 SCORE® tibial base plate for mobile bearing insert - HA coated - cementless – Size 8	ET106-001
-----------	---	-----------