

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: **2020-07-03**

Expiry Date: **2022-05-02**

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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.

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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: **2020-07-03**
 Issued To: **AMPLITUDE**
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Subcontractor:	Service(s) supplied
Acnis International 220 Rue Léon Blum Villeurbanne 69100 France	Crucial Supplier
ATS SAS ZI de Bruèges Avenue Monge BP 80286 Ales Cedex 30106 France	Crucial Supplier Manufacture
Belmonte ZAC des couleurs Chemin du Pau Valence 26000 France	Manufacture

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Subcontractor:

Service(s) supplied

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

Manufacture

DOT GmbH
 Charles-Darwin-Ring 1 a
 Rostock
 18059
 Germany

Other Critical Processes

ENTEGRIS
 395, rue Louis Lépine
 MONTPELLIER
 34000
 France

Assembly
Other Critical Processes
Packaging

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26000
France

Subcontractor:

Service(s) supplied

Eurocoating
 Via al DOS De La Roda, 60
 Pergine Valsugana
 38057
 Italy

Other Critical Processes
Packaging

Firm Industrie
 ZA Blacheronde d'Etoile
 Etoile Sur Rhone
 26800
 France

Manufacture

HTI TECHNOLOGIES
 49, Avenue Franklin Roosevelt
 DECINES
 69150
 France

Other Critical Processes

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Subcontractor:	Service(s) supplied
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)
MARLE ZI rue Lavoisier NOGENT 52800 France	Crucial Supplier Manufacture

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Subcontractor:

Service(s) supplied

Marle Finishing SAS
 443 Rue René Cassin
 La Talaudière
 42350
 France

Manufacture

Marle Finishing SAS
 22 rue de le Mollanche
 Sorbiers
 42290
 France

Manufacture
Other Critical Processes
Packaging

MediTECH Medical Polymers
 Division of Quandrant EPP
 2710 American Way
 Ft. Wayne
 Indiana
 46809
 USA

Manufacture

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France

Subcontractor:

Service(s) supplied

Microweld
 Parc Altais, Rue Uranus
 CHAVANOD
 74650
 France

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

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26000
France

Subcontractor:	Service(s) supplied
Progress Silicones ZI des Bourguignons APT 84400 France	Crucial Supplier
S.A.R.L. Devise 6 impasse Aulagnier Portes Les Valence 26800 France	Crucial Supplier
Serret Mecanique 185 Allee De L'Hermitage - Zone Industrielle SUD Bourg De Peage 26300 France	Crucial Supplier

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26000
France

Subcontractor:

Service(s) supplied

Simagec
 54 Avenue de la Plaine
 Rousset
 13106
 France

Assembly
Other Critical Processes
Packaging

Societe Mecanique Pansu
 Quartier de Brezide
 Beaumont Les Valence
 26760
 France

Crucial Supplier

STAINLESS
 4 rue Thalès
 Dannemarie-sur-Crete
 25410
 France

Crucial Supplier

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France

Subcontractor:	Service(s) supplied
SYNERGY HEALTH MARSEILLE Entrepot Min 712 Les Arnavaux MARSEILLE 13014 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

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11 Cours Jacques OFFENBACH
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VALENCE
26000
France

Subcontractor:

Service(s) supplied

Westlake Plastics Europe SAS
 159 rue de Rotterdam ZAC
 Ravennes les Francs
 Bondues
 59910
 France

Crucial Supplier

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EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 615308**
 Date: **2020-07-03**
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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.

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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 Certificate - Full Quality Assurance System

Certificate History

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Date	Reference number	Action
Current	9653997	Addition of alternative gamma sterilisation provider: IONISOS Dagneux

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

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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**

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Page 1 of 28

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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**

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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**

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Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
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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>

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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
1-0200115	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**

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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**

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

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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>

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Issued To:

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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>

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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>

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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>

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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>

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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>

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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>

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

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 <i>SCORE® II Femoral Component - Cemented - Size 0 Right</i>
1-0205201	SCORE® II Composant Fémoral - A Ciment - Taille 1 Droite <i>SCORE® II Femoral Component - Cemented - Size 1 Right</i>
1-0205202	SCORE® II Composant Fémoral - A Ciment - Taille 2 Droite <i>SCORE® II Femoral Component - Cemented - Size 2 Right</i>
1-0205203	SCORE® II Composant Fémoral - A Ciment - Taille 3 Droite <i>SCORE® II Femoral Component - Cemented - Size 3 Right</i>
1-0205204	SCORE® II Composant Fémoral - A Ciment - Taille 4 Droite <i>SCORE® II Femoral Component - Cemented - Size 4 Right</i>
1-0205205	SCORE® II Composant Fémoral - A Ciment - Taille 5 Droite <i>SCORE® II Femoral Component - Cemented - Size 5 Right</i>
1-0205206	SCORE® II Composant Fémoral - A Ciment - Taille 6 Droite <i>SCORE® II Femoral Component - Cemented - Size 6 Right</i>
1-0205207	SCORE® II Composant Fémoral - A Ciment - Taille 7 Droite <i>SCORE® II Femoral Component - Cemented - Size 7 Right</i>

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

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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>

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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>

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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>

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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>

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

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Supplementary Information to CE 615311

Issued To:

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11 Cours Jacques OFFENBACH
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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>

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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>

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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>

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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>

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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>

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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>

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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).

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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

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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.

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EC Design-Examination Certificate

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

No.**CE 643576****Issued To:****AMPLITUDE****11 Cours Jacques Offenbach****ZA Mozart 2****VALENCE****26000****France**

In respect of:

Patellar implants for Total Knee Prosthesis

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: **2016-02-11**

Date: **2020-10-16**

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Cemented resurfacing patellar implant NM

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0201430	Implant rotulien de resurfacement NM à cimenter - Ø30 mm <i>Cemented resurfacing patellar implant NM - Ø30 mm</i>
1-0201433	Implant rotulien de resurfacement NM à cimenter - Ø33 mm <i>Cemented resurfacing patellar implant NM - Ø33 mm</i>
1-0201436	Implant rotulien de resurfacement NM à cimenter - Ø36 mm <i>Cemented resurfacing patellar implant NM - Ø36 mm</i>
1-0201439	Implant rotulien de resurfacement NM à cimenter Ø39 mm <i>Cemented resurfacing patellar implant NM - Ø39 mm</i>

Cemented inset patellar implant

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0200923	Implant rotulien à encastrer à cimenter - Ø 23 mm <i>Cemented inset patellar implant - Ø 23 mm</i>
1-0200926	Implant rotulien à encastrer à cimenter - Ø 26 mm <i>Cemented inset patellar implant - Ø 26 mm</i>

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Référence Reference	Désignation Designation
1-0200929	Implant rotulien à encastrer à cimeter - Ø 29 mm <i>Cemented inset patellar implant - Ø 29 mm</i>
1-0200932	Implant rotulien à encastrer à cimeter - Ø 32 mm <i>Cemented inset patellar implant - Ø 32 mm</i>

Cemented resurfacing patellar implant Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0200830	Implant rotulien de resurfaçage à cimeter - Ø 30 mm <i>Cemented resurfacing patellar implant - Ø 30 mm</i>
1-0200833	Implant rotulien de resurfaçage à cimeter - Ø 33 mm <i>Cemented resurfacing patellar implant - Ø 33 mm</i>
1-0200836	Implant rotulien de resurfaçage à cimeter - Ø 36 mm <i>Cemented resurfacing patellar implant - Ø 36 mm</i>
1-0200839	Implant rotulien de resurfaçage à cimeter - Ø 39 mm <i>Cemented resurfacing patellar implant - Ø 39 mm</i>

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Cementless inset patellar implant

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0202123	Implant rotulien à encastrer sans ciment - Ø23 mm <i>Cementless inset patellar implant - Ø23 mm</i>
1-0202126	Implant rotulien à encastrer sans ciment - Ø26 mm <i>Cementless inset patellar implant - Ø26 mm</i>
1-0202129	Implant rotulien à encastrer sans ciment - Ø29 mm <i>Cementless inset patellar implant - Ø29 mm</i>
1-0202132	Implant rotulien à encastrer sans ciment - Ø32 mm <i>Cementless inset patellar implant - Ø32 mm</i>

Cemented asymmetric congruent resurfacing patellar implant

Material: UHMWPE complying with ISO 5834-2

Référence Reference	Désignation Designation
1-0201830	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 23x30 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 23x30 mm</i>
1-0201833	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 26x33 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 26x33 mm</i>

First Issued: **2016-02-11**

Date: **2020-10-16**

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

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Page 4 of 6

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 643576

Issued To:

AMPLITUDE
11 Cours Jacques Offenbach
ZA Mozart 2
VALENCE
26000
France

Référence Reference	Désignation Designation
1-0201836	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 29x36 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 29x36 mm</i>
1-0201839	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 32x39 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 32x39 mm</i>

Cementless asymmetric congruent inset patellar implant **Material: UHMWPE complying with ISO 5834-2**

Référence Reference	Désignation Designation
1-0210130	Implant rotulien congruent asymétrique à encastrer sans ciment - 23x30 mm <i>Cementless asymmetric congruent inset patellar implant - 23x30 mm</i>
1-0210133	Implant rotulien congruent asymétrique à encastrer sans ciment - 26x33 mm <i>Cementless asymmetric congruent inset patellar implant - 26x33 mm</i>
1-0210136	Implant rotulien congruent asymétrique à encastrer sans ciment - 29x36 mm <i>Cementless asymmetric congruent inset patellar implant - 29x36 mm</i>
1-0210139	Implant rotulien congruent asymétrique à encastrer sans ciment - 32x39 mm <i>Cementless asymmetric congruent inset patellar implant - 32x39 mm</i>

First Issued: **2016-02-11**

Date: **2020-10-16**

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

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Page 5 of 6

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EC Design-Examination Certificate

Supplementary Information to CE 643576

Issued To:

AMPLITUDE
11 Cours Jacques Offenbach
ZA Mozart 2
VALENCE
26000
France

Certificate History

Date	Reference Number	Action
11 February 2016	10158773	First issue and transfer of patella codes from CE 615311
05 March 2019	8432821	Traceable to NB 0086.
30 September 2019	9679515	Certificate Renewal
Current	9660163	Approval of new packaging configuration for the product cemented resurfacing patella – Product code 1-02008XX, cemented insert patella implant – Product code 1-02009XX, cementless insert patellar implant – Product code 1-02021XX, cemented resurfacing patellar implant NM – Product code 1-02014XX, cementless asymmetric congruent insert patellar implant – Product code 1-02101XX, cemented asymmetric congruent resurfacing patellar implant – Product code 1-02018XX Approval of AMPLITUDE 11 Cours Jacques Offenbach ZA Mozart 2 26000 Valence France as additional location for cleaning/package activities for the product ANATOMIC® fixed bearing insert – Product code 1-02047XX. Updated labelling on the above products to include MR conditional symbols.

First Issued: **2016-02-11**

Date: **2020-10-16**

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

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Page 6 of 6

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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 de première intention SCORE® <i>SCORE® primary Total Knee Prosthesis</i>	Classe du produit Classification selon la Directive 2005/50/CE Product class <i>according to classification Directive 2005/50/EC</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 <i>Device designation SCORE® femoral component PCL sacrificing – HA coated – Cementless</i> <i>SCORE® femoral component PCL sacrificing – Cemented</i> <i>SCORE® tibial base plate for mobile bearing insert – HA coated - cementless</i> <i>SCORE® tibial base plate for mobile bearing insert – Cemented</i> <i>SCORE® mobile bearing insert</i> <i>SCORE® Allergy Solution femoral component PCL sacrificing - Cemented</i> <i>SCORE® Allergy Solution tibial baseplate for mobile bearing insert - Cemented</i>		III
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 Annex I of Directive 93/42/EEC.
- ✓ Ne sont pas soumis aux Exigences de la directive 2003/32/CE introduisant des spécifications détaillées en ce qui concerne les exigences prévues par la directive 93/42/CEE du Conseil pour les dispositifs médicaux fabriqués à partir de tissus d'origine animale. De plus, aucun produit issu d'autres espèces animales que celles listées dans la directive 2003/32/CE n'est utilisé dans la composition de nos dispositifs.
Are not subject to the requirements of the Council Directive 2003/32/EC introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilizing tissues of animal origin. Moreover, our devices do not contain any products of animal origin, other than those listed in directive 2003/32/EC.
- ✓ 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.
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.

Date de mise à jour / Updated on :
2017-06-08

Procédure d'évaluation de la conformité : Annexe II, Directive 93/42/CEE :
Conformity assessment procedure: Annex 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
Délivré par : <i>Issued by:</i>	notified body 0086 BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP – UNITED KINGDOM		

Le Directeur Qualité Affaires Réglementaires / *Quality and Regulatory Affairs Director*



Mireille LEMERY

Date de 1^{ère} déclaration CE de conformité / *First EC declaration of conformity issued on:* 2003-07-08

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

SCORE® femoral component PCL sacrificing – HA coated - Cementless

Référence <i>Reference</i>	Désignation <i>Designation</i>
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>
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>

Condyle fémoral SCORE® sans conservation du LCP - A cimenter

SCORE® femoral component PCL sacrificing – Cemented

Référence <i>Reference</i>	Désignation <i>Designation</i>
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>
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>

Embase tibiale SCORE[®] pour insert mobile - HAP - sans ciment

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

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>

Embase tibiale SCORE[®] pour insert mobile - A cimenter

SCORE[®] tibial base plate for mobile bearing insert – Cemented

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>

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
DEV01-ET106

Date de mise à jour / Updated on :
2017-06-08

Insert mobile SCORE®

SCORE® mobile bearing insert

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

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

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

SCORE® Allergy Solution femoral component PCL sacrificing - Cemented

Référence <i>Reference</i>	Désignation <i>Designation</i>
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>

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
DEV01-ET106

Date de mise à jour / Updated on :
2017-06-08

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>
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>

Embase tibiale SCORE® Allergie Solution pour insert mobile - à cimenter

SCORE® Allergy Solution tibial baseplate for mobile bearing insert - Cemented

Référence <i>Reference</i>	Désignation <i>Designation</i>
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>

Date de mise à jour / Updated on :
2017-06-07

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>	Implants rotuliens pour Prothèses Totales de Genou <i>Patellar implants for Total Knee Prosthesis</i>	Classe du produit Classification selon la Directive 2005/50/CE Product class <i>according to classification Directive 2005/50/EC</i>
Désignation du dispositif : <i>Device designation</i>	Implant rotulien de resurfaçage NM à cimenter Implant rotulien à encastrer à cimenter Implant rotulien de resurfaçage à cimenter Implant rotulien à encastrer sans ciment Implant rotulien congruent asymétrique de resurfaçage à cimenter Implant rotulien congruent asymétrique à encastrer sans ciment <i>Cemented resurfacing patellar implant NM</i> <i>Cemented inset patellar implant</i> <i>Cemented resurfacing patellar implant</i> <i>Cementless inset patellar implant</i> <i>Cemented asymmetric congruent resurfacing patellar implant</i> <i>Cementless asymmetric congruent inset patellar implant</i>	III
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 sont pas soumis aux Exigences de la directive 2003/32/CE introduisant des spécifications détaillées en ce qui concerne les exigences prévues par la directive 93/42/CEE du Conseil pour les dispositifs médicaux fabriqués à partir de tissus d'origine animale. De plus, aucun produit issu d'autres espèces animales que celles listées dans la directive 2003/32/CE n'est utilisé dans la composition de nos dispositifs.
Are not subject to the requirements of the Council Directive 2003/32/EC introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilizing tissues of animal origin. Moreover, our devices do not contain any products of animal origin, other than those listed in directive 2003/32/EC.
- ✓ 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.
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.

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
Certificate Annex II excluding section 4

615308

•Certificat Annexe II.4
Annex II.4 certificate

643576

Délivré par : **notified body 0086**
Issued by:

BSI Group
Kitemark Court, Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP – UNITED KINGDOM

Le Directeur Qualité Affaires Réglementaires / Quality and Regulatory Affairs Director



Date de 1^{ère} déclaration CE de conformité / *First EC declaration of conformity issued on:* 2003-07-08

Implant rotulien de resurfacement NM à cimenter
Cemented resurfacing patellar implant NM

Référence Reference	Désignation Designation
1-0201430	Implant rotulien de resurfacement NM à cimenter - Ø30 mm <i>Cemented resurfacing patellar implant NM - Ø30 mm</i>
1-0201433	Implant rotulien de resurfacement NM à cimenter - Ø33 mm <i>Cemented resurfacing patellar implant NM - Ø33 mm</i>
1-0201436	Implant rotulien de resurfacement NM à cimenter - Ø36 mm <i>Cemented resurfacing patellar implant NM - Ø36 mm</i>
1-0201439	Implant rotulien de resurfacement NM à cimenter Ø39 mm <i>Cemented resurfacing patellar implant NM - Ø39 mm</i>

Implant rotulien à encastrer à cimenter
Cemented inset patellar implant

Référence Reference	Désignation Designation
1-0200923	Implant rotulien à encastrer à cimenter - Ø 23 mm <i>Cemented inset patellar implant - Ø 23 mm</i>
1-0200926	Implant rotulien à encastrer à cimenter - Ø 26 mm <i>Cemented inset patellar implant - Ø 26 mm</i>
1-0200929	Implant rotulien à encastrer à cimenter - Ø 29 mm <i>Cemented inset patellar implant - Ø 29 mm</i>
1-0200932	Implant rotulien à encastrer à cimenter - Ø 32 mm <i>Cemented inset patellar implant - Ø 32 mm</i>

Implant rotulien de resurfacement à cimenter
Cemented resurfacing patellar implant

Référence Reference	Désignation Designation
1-0200830	Implant rotulien de resurfacement à cimenter - Ø 30 mm <i>Cemented resurfacing patellar implant - Ø 30 mm</i>
1-0200833	Implant rotulien de resurfacement à cimenter - Ø 33 mm <i>Cemented resurfacing patellar implant - Ø 33 mm</i>
1-0200836	Implant rotulien de resurfacement à cimenter - Ø 36 mm <i>Cemented resurfacing patellar implant - Ø 36 mm</i>
1-0200839	Implant rotulien de resurfacement à cimenter - Ø 39 mm <i>Cemented resurfacing patellar implant - Ø 39 mm</i>

Implant rotulien à encastrer sans ciment
Cementless inset patellar implant

Référence Reference	Désignation Designation
1-0202123	Implant rotulien à encastrer sans ciment - Ø23 mm <i>Cementless inset patellar implant - Ø23 mm</i>
1-0202126	Implant rotulien à encastrer sans ciment - Ø26 mm <i>Cementless inset patellar implant - Ø26 mm</i>
1-0202129	Implant rotulien à encastrer sans ciment - Ø29 mm <i>Cementless inset patellar implant - Ø29 mm</i>
1-0202132	Implant rotulien à encastrer sans ciment - Ø32 mm <i>Cementless inset patellar implant - Ø32 mm</i>

Implant rotulien congruent asymétrique de resurfaçage à cimenter
Cemented asymmetric congruent resurfacing patellar implant

Référence Reference	Désignation Designation
1-0201830	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 23x30 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 23x30 mm</i>
1-0201833	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 26x33 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 26x33 mm</i>
1-0201836	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 29x36 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 29x36 mm</i>
1-0201839	Implant rotulien congruent asymétrique de resurfaçage à cimenter - 32x39 mm <i>Cemented asymmetric congruent resurfacing patellar implant - 32x39 mm</i>

Implant rotulien congruent asymétrique à encastrer sans ciment
Cementless asymmetric congruent inset patellar implant

Référence Reference	Désignation Designation
1-0210130	Implant rotulien congruent asymétrique à encastrer sans ciment - 23x30 mm <i>Cementless asymmetric congruent inset patellar implant - 23x30 mm</i>
1-0210133	Implant rotulien congruent asymétrique à encastrer sans ciment - 26x33 mm <i>Cementless asymmetric congruent inset patellar implant - 26x33 mm</i>
1-0210136	Implant rotulien congruent asymétrique à encastrer sans ciment - 29x36 mm <i>Cementless asymmetric congruent inset patellar implant - 29x36 mm</i>
1-0210139	Implant rotulien congruent asymétrique à encastrer sans ciment - 32x39 mm <i>Cementless asymmetric congruent inset patellar implant - 32x39 mm</i>



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
Certificate Annex II excluding section 4

615308

•Certificat Annexe II.4
Annex II.4 certificate

615311
615314

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Délivré par : **notified body 2797**
Issued by:

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**

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

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

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

Insert mobile SCORE[®]
SCORE[®] mobile bearing insert

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

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

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

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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

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

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

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 10mm <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

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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

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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

AMPLITUDE
11 Cours Jacques Offenbach
ZA Mozart 2
VALENCE
26000
France



Holds Certificate Number:

MD 615264

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacturing and distribution of orthopaedic/joint implants, surgical instruments and computer assisted surgery systems.

Previous certificate expires on 28/02/2019.
Transition audit ended 28/11/2018.

Stewart Brain

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

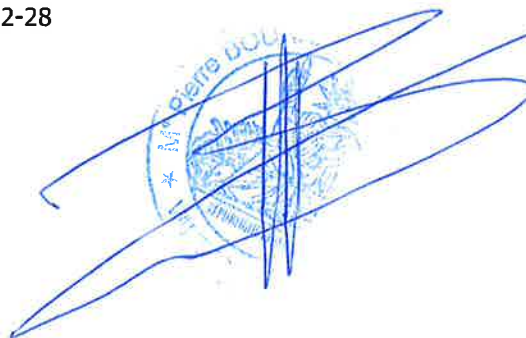
Original Registration Date: 2015-04-25

Latest Revision Date: 2019-02-28

Effective Date: 2019-02-28

Expiry Date: 2022-02-27

Page: 1 of 1



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Certification de signature

Me. BOURRICAND, notaire associé à VALENCE (26000)
certifie la signature apposée sur le présent document

comme émanant bien de :

M. Olivier JALLABERT

Cette certification n'a pour objet qu'une reconnaissance
matérielle de la signature de la personne surnommée

en sorte que cette formalité ne préjuge en rien de la
validité du document qui a été présenté au notaire.

Valence, le 02/04/19

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of use.
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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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EC Design-Examination Certificate

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

No.**CE 615329****Issued To:****AMPLITUDE****11 Cours Jacques OFFENBACH****ZA Mozart 2****VALENCE****26000****France**

In respect of:

UNI SCORE® Unicompartmental Knee Prosthesis

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: **2015-06-02**

Date: **2020-10-16**

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

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
Condyle fémoral UNI SCORE® - HAP - sans ciment UNI SCORE® femoral component - HA coated - cementless				
1-0202201	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 1 <i>UNI SCORE® femoral component - HA coated - cementless - Size 1</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202202	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 2 <i>UNI SCORE® femoral component - HA coated - cementless - Size 2</i>			
1-0202203	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 3 <i>UNI SCORE® femoral component - HA coated - cementless - Size 3</i>			
1-0202204	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 4 <i>UNI SCORE® femoral component - HA coated - cementless - Size 4</i>			
1-0202205	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 5 <i>UNI SCORE® femoral component - HA coated - cementless - Size 5</i>			
1-0202206	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 6 <i>UNI SCORE® femoral component - HA coated - cementless - Size 6</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202207	Condyle fémoral UNI SCORE® - HAP - sans ciment - Taille 7 <i>UNI SCORE® femoral component - HA coated - cementless - Size 7</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
Condyle fémoral UNI SCORE® - A cimenter UNI SCORE® femoral component - Cemented				
1-0202301	Condyle fémoral UNI SCORE® - A cimenter - Taille 1 <i>UNI SCORE® femoral component - Cemented - Size 1</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202302	Condyle fémoral UNI SCORE® - A cimenter - Taille 2 <i>UNI SCORE® femoral component - Cemented - Size 2</i>			
1-0202303	Condyle fémoral UNI SCORE® - A cimenter - Taille 3 <i>UNI SCORE® femoral component - Cemented - Size 3</i>			
1-0202304	Condyle fémoral UNI SCORE® - A cimenter - Taille 4 <i>UNI SCORE® femoral component - Cemented - Size 4</i>			
1-0202305	Condyle fémoral UNI SCORE® - A cimenter - Taille 5 <i>UNI SCORE® femoral component - Cemented - Size 5</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202306	Condyle fémoral UNI SCORE® - A cimenter - Taille 6 <i>UNI SCORE® femoral component - Cemented - Size 6</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202307	Condyle fémoral UNI SCORE® - A cimenter - Taille 7 <i>UNI SCORE® femoral component - Cemented - Size 7</i>			
Embase tibiale UNI SCORE® pour insert fixe - A cimenter UNI SCORE® tibial tray for fixed bearing insert - cemented				
1-0202501	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 1 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 1</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202502	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 2 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 2</i>			
1-0202503	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 3 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 3</i>			
1-0202504	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 4 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 4</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202505	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 5 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 5</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202506	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 6 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 6</i>			
1-0202507	Embase tibiale UNI SCORE® pour insert fixe - A cimenter - Taille 7 <i>UNI SCORE® tibial tray for fixed bearing insert - Cemented - Size 7</i>			
Insert tibial fixe UNI SCORE® UNI SCORE® tibial fixed bearing insert				
1-0202621	Insert tibial fixe UNI SCORE® - Taille 1 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 1 - Thickness 9 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202631	Insert tibial fixe UNI SCORE® - Taille 1 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 1 - Thickness 10 mm</i>			
1-0202641	Insert tibial fixe UNI SCORE® - Taille 1 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 1 - Thickness 11 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202651	Insert tibial fixe UNI SCORE® - Taille 1 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 1 - Thickness 12 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202622	Insert tibial fixe UNI SCORE® - Taille 2 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 2 - Thickness 9 mm</i>			
1-0202632	Insert tibial fixe UNI SCORE® - Taille 2 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 2 - Thickness 10 mm</i>			
1-0202642	Insert tibial fixe UNI SCORE® - Taille 2 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 2 - Thickness 11 mm</i>			
1-0202652	Insert tibial fixe UNI SCORE® - Taille 2 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 2 - Thickness 12 mm</i>			
1-0202623	Insert tibial fixe UNI SCORE® - Taille 3 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 3 - Thickness 9 mm</i>			
1-0202633	Insert tibial fixe UNI SCORE® - Taille 3 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 3 - Thickness 10 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202643	Insert tibial fixe UNI SCORE® - Taille 3 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 3 - Thickness 11 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202653	Insert tibial fixe UNI SCORE® - Taille 3 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 3 - Thickness 12 mm</i>			
1-0202624	Insert tibial fixe UNI SCORE® - Taille 4 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 4 - Thickness 9 mm</i>			
1-0202634	Insert tibial fixe UNI SCORE® - Taille 4 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 4 - Thickness 10 mm</i>			
1-0202644	Insert tibial fixe UNI SCORE® - Taille 4 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 4 - Thickness 11 mm</i>			
1-0202654	Insert tibial fixe UNI SCORE® - Taille 4 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 4 - Thickness 12 mm</i>			
1-0202625	Insert tibial fixe UNI SCORE® - Taille 5 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 5 - Thickness 9 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202635	Insert tibial fixe UNI SCORE® - Taille 5 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 5 - Thickness 10 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202645	Insert tibial fixe UNI SCORE® - Taille 5 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 5 - Thickness 11 mm</i>			
1-0202655	Insert tibial fixe UNI SCORE® - Taille 5 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 5 - Thickness 12 mm</i>			
1-0202626	Insert tibial fixe UNI SCORE® - Taille 6 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 6 - Thickness 9 mm</i>			
1-0202636	Insert tibial fixe UNI SCORE® - Taille 6 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 6 - Thickness 10 mm</i>			
1-0202646	Insert tibial fixe UNI SCORE® - Taille 6 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 6 - Thickness 11 mm</i>			
1-0202656	Insert tibial fixe UNI SCORE® - Taille 6 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 6 - Thickness 12 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202627	Insert tibial fixe UNI SCORE® - Taille 7 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert - Size 7 - Thickness 9 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202637	Insert tibial fixe UNI SCORE® - Taille 7 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert - Size 7 - Thickness 10 mm</i>			
1-0202647	Insert tibial fixe UNI SCORE® - Taille 7 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert - Size 7 - Thickness 11 mm</i>			
1-0202657	Insert tibial fixe UNI SCORE® - Taille 7 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert - Size 7 - Thickness 12 mm</i>			
Implant tibial tout PE UNI SCORE® UNI SCORE® all-poly tibial component				
1-0202811	Implant tibial tout PE Uni SCORE® - Taille 1 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 1 - Thickness 8 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202821	Implant tibial tout PE Uni SCORE® - Taille 1 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 9 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202831	Implant tibial tout PE Uni SCORE® - Taille 1 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 1 - Thickness 10 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202841	Implant tibial tout PE Uni SCORE® - Taille 1 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 1 - Thickness 11 mm</i>			
1-0202851	Implant tibial tout PE Uni SCORE® - Taille 1 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 1 - Thickness 12 mm</i>			
1-0202812	Implant tibial tout PE Uni SCORE® - Taille 2 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 2 - Thickness 8 mm</i>			
1-0202822	Implant tibial tout PE Uni SCORE® - Taille 2 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 2 - Thickness 9 mm</i>			
1-0202832	Implant tibial tout PE Uni SCORE® - Taille 2 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 2 - Thickness 10 mm</i>			
1-0202842	Implant tibial tout PE Uni SCORE® - Taille 2 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 2 - Thickness 11 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202852	Implant tibial tout PE Uni SCORE® - Taille 2 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 2 - Thickness 12 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202813	Implant tibial tout PE Uni SCORE® - Taille 3 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 3 - Thickness 8 mm</i>			
1-0202823	Implant tibial tout PE Uni SCORE® - Taille 3 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 3 - Thickness 9 mm</i>			
1-0202833	Implant tibial tout PE Uni SCORE® - Taille 3 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 3 - Thickness 10 mm</i>			
1-0202843	Implant tibial tout PE Uni SCORE® - Taille 3 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 3 - Thickness 11 mm</i>			
1-0202853	Implant tibial tout PE Uni SCORE® - Taille 3 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 3 - Thickness 12 mm</i>			
1-0202814	Implant tibial tout PE Uni SCORE® - Taille 4 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 4 - Thickness 8 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202824	Implant tibial tout PE Uni SCORE® - Taille 4 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 4 - Thickness 9 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202834	Implant tibial tout PE Uni SCORE® - Taille 4 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 4 - Thickness 10 mm</i>			
1-0202844	Implant tibial tout PE Uni SCORE® - Taille 4 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 4 - Thickness 11 mm</i>			
1-0202854	Implant tibial tout PE Uni SCORE® - Taille 4 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 4 - Thickness 12 mm</i>			
1-0202815	Implant tibial tout PE Uni SCORE® - Taille 5 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 5 - Thickness 8 mm</i>			
1-0202825	Implant tibial tout PE Uni SCORE® - Taille 5 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 5 - Thickness 9 mm</i>			
1-0202835	Implant tibial tout PE Uni SCORE® - Taille 5 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 5 - Thickness 10 mm</i>			

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Date: **2020-10-16**

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

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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 615329

Issued To:

AMPLITUDE
11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
France

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202845	Implant tibial tout PE Uni SCORE® - Taille 5 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 5 - Thickness 11 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202855	Implant tibial tout PE Uni SCORE® - Taille 5 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 5 - Thickness 12 mm</i>			
1-0202816	Implant tibial tout PE Uni SCORE® - Taille 6 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 6 - Thickness 8 mm</i>			
1-0202826	Implant tibial tout PE Uni SCORE® - Taille 6 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 6 - Thickness 9 mm</i>			
1-0202836	Implant tibial tout PE Uni SCORE® - Taille 6 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 6 - Thickness 10 mm</i>			
1-0202846	Implant tibial tout PE Uni SCORE® - Taille 6 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 6 - Thickness 11 mm</i>			
1-0202856	Implant tibial tout PE Uni SCORE® - Taille 6 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 6 - Thickness 12 mm</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0202817	Implant tibial tout PE Uni SCORE® - Taille 7 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component - Size 7 - Thickness 8 mm</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0202827	Implant tibial tout PE Uni SCORE® - Taille 7 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component - Size 7 - Thickness 9 mm</i>			
1-0202837	Implant tibial tout PE Uni SCORE® - Taille 7 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component - Size 7 - Thickness 10 mm</i>			
1-0202847	Implant tibial tout PE Uni SCORE® - Taille 7 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component - Size 7 - Thickness 11 mm</i>			
1-0202857	Implant tibial tout PE Uni SCORE® - Taille 7 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component - Size 7 - Thickness 12 mm</i>			
Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment (à plot) UNI SCORE® tibial tray for fixed bearing insert - HA coated - Cementless (with peg)				
1-0205701	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment - Taille 1 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated - Cementless - Size 1 RM / LL</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0205702	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 2 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 2 RM / LL</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0205703	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 3 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 3 RM / LL</i>			
1-0205704	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 4 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 4 RM / LL</i>			
1-0205705	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 5 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 5 RM / LL</i>			
1-0205706	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 6 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 6 RM / LL</i>			
1-0205707	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 7 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 7 RM / LL</i>			
1-0205801	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 1 IND /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 1 LM/ RL</i>			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
1-0205802	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 2 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 2 LM/ RL</i>	Unicompartmental Knee Prosthesis	Medical device intended for the replacement for one side of the femoro-tibial joints of the knee	III
1-0205803	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 3 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 3 LM/ RL</i>			
1-0205804	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 4 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 4 LM/ RL</i>			
1-0205805	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 5 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 5 LM/ RL</i>			
1-0205806	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 6 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 6 LM/ RL</i>			
1-0205807	Embase tibiale UNI SCORE® pour insert fixe – HAP - sans ciment - Taille 7 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert - HA coated – Cementless - Size 7 LM/ RL</i>			

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11 Cours Jacques OFFENBACH
ZA Mozart 2
VALENCE
26000
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Certificate History

Date	Reference Number	Action
02 June 2015	10147078	First issue, transfer from another Notified Body.
04 December 2016	10166474	Packaging Change affecting product codes: #1-02022XX, #1-02023XX, #1-02029XX, #1-02030XX, #1-02025XX, #1-02059XX / 1-02060XX and #1-02057XX / 1-02058XX.
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.
01 November 2019	9646511	Certificate Renewal. Updated the Product specific details chart in the supplementary Information to align with the new format. Removed the following devices: Tibial tray for mobile bearing insert cementless and cemented (1-02029XX, 1-02030XX, 1-02059XX, and 1-02060XX), the tibial mobile bearing insert (1-02027XX), and the tibial tray for fixed bearing insert - HA coated - cementless (1-02024XX).

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Date	Reference Number	Action
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 both original and additional sterilisation sites). This change is applicable to the following devices: • UNISCORE® Femoral component cementless • UNISCORE® Tibial tray for fixed bearing insert cementless with peg • UNISCORE® Femoral component cemented • UNISCORE® Tibial tray for fixed bearing insert cemented
Current	9660163	Approval of new packaging configuration for the product UNI SCORE® tibial fixed bearing insert - Product code 1-02026XX and UNI SCORE® all –poly tibial component – Product code 1-02028XX. Approval of AMPLITUDE 11 Cours Jacques Offenbach ZA Mozart 2 26000 Valence France as additional location for cleaning/packaging activities for the product UNI SCORE® tibial fixed bearing insert - Product code 1-02026XX and UNI SCORE® all –poly tibial component – Product code 1-02028XX. Updated labelling on the above products to include MR conditional symbols.

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04-NOV-2019

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 de Genou unicompartimentale UNI SCORE® <i>UNI SCORE® unicompartmental Knee prosthesis</i>	Classe du produit <i>Product class</i> III
Désignation du dispositif : Condyle fémoral UNI SCORE® - HAP - sans ciment Condyle fémoral UNI SCORE® - A cimenter Embase tibiale UNI SCORE® pour insert fixe - A cimenter Insert tibial fixe UNI SCORE® Implant tibial tout PE UNI SCORE® Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment (à plot) <i>Device designation</i> UNI SCORE® femoral component – HA coated - cementless UNI SCORE® femoral component – Cemented UNI SCORE® tibial tray for fixed bearing insert – HA coated - cementless UNI SCORE® tibial tray for fixed bearing insert – cemented UNI SCORE® tibial tray for mobile bearing insert – HA coated - cementless UNI SCORE® tibial tray for mobile bearing insert – Cemented UNI SCORE® tibial fixed bearing insert UNI SCORE® tibial mobile bearing insert UNI SCORE® all-poly tibial component UNI SCORE® tibial tray for fixed bearing insert – HA coated - Cementless (with peg) UNI SCORE® tibial tray for mobile bearing insert – HA coated – Cementless (with peg) Référence(s) : Voir liste ci-jointe. <i>Reference(s): See enclosed list.</i>		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

- ✓ 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 Annex 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.
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

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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: Annex II, Directive 93/42/EEC

•Certificat Annexe II section 4 exclue
Certificate Annex II excluding section 4

615308

•Certificat Annexe II.4
Annex II.4 certificate

615329

Délivré par : **notified body 2797**
Issued by:

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Le Directeur Qualité Affaires Réglementaires / Quality and Regulatory Affairs Director



Mireille LEMERY

Date de 1^{ère} déclaration CE de conformité / *First EC declaration of conformity issued on:* 2007-05-28

Condyle fémoral UNI SCORE[®] - HAP - sans ciment

UNI SCORE[®] femoral component – HA coated – cementless

Référence Reference	Désignation Designation
1-0202201	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 1 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 1</i>
1-0202202	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 2 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 2</i>
1-0202203	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 3 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 3</i>
1-0202204	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 4 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 4</i>
1-0202205	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 5 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 5</i>
1-0202206	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 6 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 6</i>
1-0202207	Condyle fémoral UNI SCORE [®] - HAP - sans ciment – Taille 7 <i>UNI SCORE[®] femoral component – HA coated – cementless – Size 7</i>

Condyle fémoral UNI SCORE[®] - A cimenter

UNI SCORE[®] femoral component – Cemented

Référence Reference	Désignation Designation
1-0202301	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 1 <i>UNI SCORE[®] femoral component – Cemented – Size 1</i>
1-0202302	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 2 <i>UNI SCORE[®] femoral component – Cemented – Size 2</i>
1-0202303	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 3 <i>UNI SCORE[®] femoral component – Cemented – Size 3</i>
1-0202304	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 4 <i>UNI SCORE[®] femoral component – Cemented – Size 4</i>
1-0202305	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 5 <i>UNI SCORE[®] femoral component – Cemented – Size 5</i>
1-0202306	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 6 <i>UNI SCORE[®] femoral component – Cemented – Size 6</i>
1-0202307	Condyle fémoral UNI SCORE [®] - A cimenter – Taille 7 <i>UNI SCORE[®] femoral component – Cemented – Size 7</i>

Embase tibiale UNI SCORE® pour insert fixe - A cimenter

UNI SCORE® tibial tray for fixed bearing insert – cemented

Référence Reference	Désignation Designation
1-0202501	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 1 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 1</i>
1-0202502	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 2 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 2</i>
1-0202503	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 3 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 3</i>
1-0202504	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 4 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 4</i>
1-0202505	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 5 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 5</i>
1-0202506	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 6 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 6</i>
1-0202507	Embase tibiale UNI SCORE® pour insert fixe - A cimenter – Taille 7 <i>UNI SCORE® tibial tray for fixed bearing insert – Cemented - Size 7</i>

Insert tibial fixe UNI SCORE®

UNI SCORE® tibial fixed bearing insert

Référence Reference	Désignation Designation
1-0202621	Insert tibial fixe UNI SCORE® – Taille 1 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 1 - Thickness 9 mm</i>
1-0202631	Insert tibial fixe UNI SCORE® – Taille 1 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 1 - Thickness 10 mm</i>
1-0202641	Insert tibial fixe UNI SCORE® – Taille 1 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 1 - Thickness 11 mm</i>
1-0202651	Insert tibial fixe UNI SCORE® – Taille 1 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 1 - Thickness 12 mm</i>
1-0202622	Insert tibial fixe UNI SCORE® – Taille 2 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 2 - Thickness 9 mm</i>
1-0202632	Insert tibial fixe UNI SCORE® – Taille 2 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 2 - Thickness 10 mm</i>
1-0202642	Insert tibial fixe UNI SCORE® – Taille 2 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 2 - Thickness 11 mm</i>
1-0202652	Insert tibial fixe UNI SCORE® – Taille 2 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 2 - Thickness 12 mm</i>
1-0202623	Insert tibial fixe UNI SCORE® – Taille 3 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 3 - Thickness 9 mm</i>
1-0202633	Insert tibial fixe UNI SCORE® – Taille 3 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 3 - Thickness 10 mm</i>
1-0202643	Insert tibial fixe UNI SCORE® – Taille 3 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 3 - Thickness 11 mm</i>
1-0202653	Insert tibial fixe UNI SCORE® – Taille 3 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 3 - Thickness 12 mm</i>

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET136-001

Date de mise à jour / Updated on :
04-NOV-2019

Référence Reference	Désignation Designation
1-0202624	Insert tibial fixe UNI SCORE® – Taille 4 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 4 - Thickness 9 mm</i>
1-0202634	Insert tibial fixe UNI SCORE® – Taille 4 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 4 - Thickness 10 mm</i>
1-0202644	Insert tibial fixe UNI SCORE® – Taille 4 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 4 - Thickness 11 mm</i>
1-0202654	Insert tibial fixe UNI SCORE® – Taille 4 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 4 - Thickness 12 mm</i>
1-0202625	Insert tibial fixe UNI SCORE® – Taille 5 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 5 - Thickness 9 mm</i>
1-0202635	Insert tibial fixe UNI SCORE® – Taille 5 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 5 - Thickness 10 mm</i>
1-0202645	Insert tibial fixe UNI SCORE® – Taille 5 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 5 - Thickness 11 mm</i>
1-0202655	Insert tibial fixe UNI SCORE® – Taille 5 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 5 - Thickness 12 mm</i>
1-0202626	Insert tibial fixe UNI SCORE® – Taille 6 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 6 - Thickness 9 mm</i>
1-0202636	Insert tibial fixe UNI SCORE® – Taille 6 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 6 - Thickness 10 mm</i>
1-0202646	Insert tibial fixe UNI SCORE® – Taille 6 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 6 - Thickness 11 mm</i>
1-0202656	Insert tibial fixe UNI SCORE® – Taille 6 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 6 - Thickness 12 mm</i>
1-0202627	Insert tibial fixe UNI SCORE® – Taille 7 - Epaisseur 9 mm <i>UNI SCORE® tibial fixed bearing insert – Size 7 - Thickness 9 mm</i>
1-0202637	Insert tibial fixe UNI SCORE® – Taille 7 - Epaisseur 10 mm <i>UNI SCORE® tibial fixed bearing insert – Size 7 - Thickness 10 mm</i>
1-0202647	Insert tibial fixe UNI SCORE® – Taille 7 - Epaisseur 11 mm <i>UNI SCORE® tibial fixed bearing insert – Size 7 - Thickness 11 mm</i>
1-0202657	Insert tibial fixe UNI SCORE® – Taille 7 - Epaisseur 12 mm <i>UNI SCORE® tibial fixed bearing insert – Size 7 - Thickness 12 mm</i>

Implant tibial tout PE UNI SCORE®

UNI SCORE® all-poly tibial component

Référence Reference	Désignation Designation
1-0202811	Implant tibial tout PE Uni SCORE® – Taille 1 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 8 mm</i>
1-0202821	Implant tibial tout PE Uni SCORE® – Taille 1 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 9 mm</i>
1-0202831	Implant tibial tout PE Uni SCORE® – Taille 1 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 10 mm</i>
1-0202841	Implant tibial tout PE Uni SCORE® – Taille 1 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 11 mm</i>
1-0202851	Implant tibial tout PE Uni SCORE® – Taille 1 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 1 - Thickness 12 mm</i>
1-0202812	Implant tibial tout PE Uni SCORE® – Taille 2 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 2 - Thickness 8 mm</i>
1-0202822	Implant tibial tout PE Uni SCORE® – Taille 2 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 2 - Thickness 9 mm</i>
1-0202832	Implant tibial tout PE Uni SCORE® – Taille 2 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 2 - Thickness 10 mm</i>
1-0202842	Implant tibial tout PE Uni SCORE® – Taille 2 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 2 - Thickness 11 mm</i>
1-0202852	Implant tibial tout PE Uni SCORE® – Taille 2 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 2 - Thickness 12 mm</i>
1-0202813	Implant tibial tout PE Uni SCORE® – Taille 3 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 3 - Thickness 8 mm</i>
1-0202823	Implant tibial tout PE Uni SCORE® – Taille 3 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 3 - Thickness 9 mm</i>
1-0202833	Implant tibial tout PE Uni SCORE® – Taille 3 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 3 - Thickness 10 mm</i>
1-0202843	Implant tibial tout PE Uni SCORE® – Taille 3 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 3 - Thickness 11 mm</i>
1-0202853	Implant tibial tout PE Uni SCORE® – Taille 3 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 3 - Thickness 12 mm</i>
1-0202814	Implant tibial tout PE Uni SCORE® – Taille 4 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 4 - Thickness 8 mm</i>
1-0202824	Implant tibial tout PE Uni SCORE® – Taille 4 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 4 - Thickness 9 mm</i>
1-0202834	Implant tibial tout PE Uni SCORE® – Taille 4 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 4 - Thickness 10 mm</i>
1-0202844	Implant tibial tout PE Uni SCORE® – Taille 4 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 4 - Thickness 11 mm</i>
1-0202854	Implant tibial tout PE Uni SCORE® – Taille 4 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 4 - Thickness 12 mm</i>
1-0202815	Implant tibial tout PE Uni SCORE® – Taille 5 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 5 - Thickness 8 mm</i>
1-0202825	Implant tibial tout PE Uni SCORE® – Taille 5 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 5 - Thickness 9 mm</i>

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Dossier / File :
ET136-001

Date de mise à jour / Updated on :
04-NOV-2019

Référence Reference	Désignation Designation
1-0202835	Implant tibial tout PE Uni SCORE® – Taille 5 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 5 - Thickness 10 mm</i>
1-0202845	Implant tibial tout PE Uni SCORE® – Taille 5 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 5 - Thickness 11 mm</i>
1-0202855	Implant tibial tout PE Uni SCORE® – Taille 5 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 5 - Thickness 12 mm</i>
1-0202816	Implant tibial tout PE Uni SCORE® – Taille 6 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 6 - Thickness 8 mm</i>
1-0202826	Implant tibial tout PE Uni SCORE® – Taille 6 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 6 - Thickness 9 mm</i>
1-0202836	Implant tibial tout PE Uni SCORE® – Taille 6 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 6 - Thickness 10 mm</i>
1-0202846	Implant tibial tout PE Uni SCORE® – Taille 6 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 6 - Thickness 11 mm</i>
1-0202856	Implant tibial tout PE Uni SCORE® – Taille 6 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 6 - Thickness 12 mm</i>
1-0202817	Implant tibial tout PE Uni SCORE® – Taille 7 - Epaisseur 8 mm <i>UNI SCORE® all-poly tibial component – Size 7 - Thickness 8 mm</i>
1-0202827	Implant tibial tout PE Uni SCORE® – Taille 7 - Epaisseur 9 mm <i>UNI SCORE® all-poly tibial component – Size 7 - Thickness 9 mm</i>
1-0202837	Implant tibial tout PE Uni SCORE® – Taille 7 - Epaisseur 10 mm <i>UNI SCORE® all-poly tibial component – Size 7 - Thickness 10 mm</i>
1-0202847	Implant tibial tout PE Uni SCORE® – Taille 7 - Epaisseur 11 mm <i>UNI SCORE® all-poly tibial component – Size 7 - Thickness 11 mm</i>
1-0202857	Implant tibial tout PE Uni SCORE® – Taille 7 - Epaisseur 12 mm <i>UNI SCORE® all-poly tibial component – Size 7 - Thickness 12 mm</i>

Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment (à plot)

UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless (with peg)

Référence Reference	Désignation Designation
1-0205701	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 1 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 1 RM / LL</i>
1-0205702	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 2 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 2 RM / LL</i>
1-0205703	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 3 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 3 RM / LL</i>
1-0205704	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 4 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 4 RM / LL</i>
1-0205705	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 5 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 5 RM / LL</i>
1-0205706	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 6 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 6 RM / LL</i>
1-0205707	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 7 IND /EXG <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 7 RM / LL</i>
1-0205801	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 1 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 1 LM/ RL</i>
1-0205802	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 2 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 2 LM/ RL</i>
1-0205803	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 3 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 3 LM/ RL</i>
1-0205804	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 4 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 4 LM/ RL</i>
1-0205805	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 5 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 5 LM/ RL</i>
1-0205806	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 6 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 6 LM/ RL</i>
1-0205807	Embase tibiale UNI SCORE® pour insert fixe - HAP - sans ciment – Taille 7 ING /EXD <i>UNI SCORE® tibial tray for fixed bearing insert – HA coated – Cementless – Size 7 LM/ RL</i>