

MANUFACTURER		
Name of Company	Adress	SRN
Ortho CAPE	172 Imp. Louis Lépine, 82000 Montauban - France	FR-MF-000028862

Nous, le fabricant, déclarons sous sa seule responsabilité, que les produits listés ci-dessus répondent aux dispositions applicables, en particulier aux exigences générales de sécurité et de performance du Règlement (UE) 2017/745 du Parlement Européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux et au code de la santé publique.

We, the manufacturer, declare under its only responsibility that above named products meets the applicable provisions, in particular the general safety and performance requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Public Health Code.

IMPLANTS FOR FOOT SURGERY				
PPDA Screws Ø 3				
N°	English trade name	French trade name	Reference	UDI-DI
01	PPDA Screw Ø3 lg 10	vis PPDA Ø3 lg 10mm	38.65.10	3760347450155
02	PPDA Screw Ø3 lg 12	vis PPDA Ø3 lg 12mm	38.65.12	3760347450162
03	PPDA Screw Ø3 lg 14	vis PPDA Ø3 lg 14mm	38.65.14	3760347450179
04	PPDA Screw Ø3 lg 16	vis PPDA Ø3 lg 16mm	38.65.16	3760347450186
05	PPDA Screw Ø3 lg 18	vis PPDA Ø3 lg 18mm	38.65.18	3760347450193
06	PPDA Screw Ø3 lg 20	vis PPDA Ø3 lg 20mm	38.65.20	3760347450209
07	PPDA Screw Ø3 lg 22	vis PPDA Ø3 lg 22mm	38.65.22	3760347450216
08	PPDA Screw Ø3 lg 24	vis PPDA Ø3 lg 24mm	38.65.24	3760347450223
09	PPDA Screw Ø3 lg 26	vis PPDA Ø3 lg 26mm	38.65.26	3760347450230
10	PPDA Screw Ø3 Lg 28	Vis PPDA Ø3 Lg 28mm	38.65.28	3760347450247
11	PPDA Screw Ø3 Lg 30	Vis PPDA Ø3 Lg 30mm	38.65.30	3760347450254
12	PPDA Screw Ø3 Lg 32	Vis PPDA Ø3 Lg 32mm	38.65.32	3760347450278
13	PPDA Screw Ø3 Lg 34	Vis PPDA Ø3 Lg 34mm	38.65.34	3760347450261
PPDA Screws Ø 2.6				
01	PPDA Screw Ø 2.6 lg 10	vis PPDA Ø2.6 lg 10 mm	38.49.10	3760347450285
02	PPDA Screw Ø 2.6 lg 12	vis PPDA Ø2.6 lg 12 mm	38.49.12	3760347450292
03	PPDA Screw Ø 2.6 lg 14	vis PPDA Ø2.6 lg 14 mm	38.49.14	3760347450308
04	PPDA Screw Ø 2.6 lg 16	vis PPDA Ø2.6 lg 16 mm	38.49.16	3760347450315
05	PPDA Screw Ø 2.6 lg 18	vis PPDA Ø2.6 lg 18 mm	38.49.18	3760347450322
06	PPDA Screw Ø 2.6 lg 20	vis PPDA Ø2.6 lg 20 mm	38.49.20	3760347450339
07	PPDA Screw Ø 2.6 lg 22	vis PPDA Ø2.6 lg 22 mm	38.49.22	3760347450346
08	PPDA Screw Ø 2.6 lg 24	vis PPDA Ø2.6 lg 24 mm	38.49.24	3760347450353
09	PPDA Screw Ø 2.6 lg 26	vis PPDA Ø2.6 lg 26 mm	38.49.26	3760347450360
10	PPDA Screw Ø 2.6 lg 28	vis PPDA Ø2.6 lg 28 mm	38.49.28	3760347450377
11	PPDA Screw Ø 2.6 lg 30	vis PPDA Ø2.6 lg 30 mm	38.49.30	3760347450384

12	PPDA Screw Ø 2.6 lg 32	vis PPDA Ø2.6 lg 32 mm	38.49.32	3760347450391
13	PPDA Screw Ø 2.6 lg 34	vis PPDA Ø2.6 lg 34 mm	38.49.34	3760347450407
MI- Screw Ø 3				
01	MI SCREW Ø3 lg 18	vis MI SCREW Ø3 lg 18mm	32.92.18	3760347450414
02	MI SCREW Ø3 lg 20	vis MI SCREW Ø3 lg 20 mm	32.92.20	3760347450421
03	MI SCREW Ø3 lg 22	vis MI SCREW Ø3 lg 22 mm	32.92.22	3760347450438
04	MI SCREW Ø3 lg 24	vis MI SCREW Ø3 lg 24mm	32.92.24	3760347450445
05	MI SCREW Ø3 lg 26	vis MI SCREW Ø3 lg 26 mm	32.92.26	3760347450452
06	MI SCREW Ø3 lg 28	vis MI SCREW Ø3 lg 28 mm	32.92.28	3760347450469
07	MI SCREW Ø3 lg 30	vis MI SCREW Ø3 lg 30 mm	32.92.30	3760347450476
08	MI SCREW Ø3 lg 32	vis MI SCREW Ø3 lg 32 mm	32.92.32	3760347450483
09	MI SCREW Ø3 lg 34	vis MI SCREW Ø3 lg 34 mm	32.92.34	3760347450490
10	MI SCREW Ø3 lg 36	vis MI SCREW Ø3 lg 36 mm	32.92.36	3760347450506
11	MI SCREW Ø3 lg 38	vis MI SCREW Ø3 lg 38 mm	32.92.38	3760347450513
12	MI SCREW Ø3 lg 40	vis MI SCREW Ø3 lg 40 mm	32.92.40	3760347450520
13	MI SCREW Ø3 lg 42	vis MI SCREW Ø3 lg 42 mm	32.92.42	3760347450537
14	MI SCREW Ø3 lg 44	vis MI SCREW Ø3 lg 44 mm	32.92.44	3760347450544
15	MI SCREW Ø3 lg 46	vis MI SCREW Ø3 lg 46 mm	32.92.46	3760347450551
16	MI SCREW Ø3 lg 48	vis MI SCREW Ø3 lg 48 mm	32.92.48	3760347450568
17	MI SCREW Ø3 lg 50	vis MI SCREW Ø3 lg 50 mm	32.92.50	3760347450575
18	MI SCREW Ø3 lg 52	vis MI SCREW Ø3 lg 52 mm	32.92.52	3760347450582
19	MI SCREW Ø3 lg 54	vis MI SCREW Ø3 lg 54 mm	32.92.54	3760347450599
20	MI SCREW Ø3 lg 56	vis MI SCREW Ø3 lg 56 mm	32.92.56	3760347450605
21	MI SCREW Ø3 lg 58	vis MI SCREW Ø3 lg 58 mm	32.92.58	3760347450612
22	MI SCREW Ø3 lg 60	vis MI SCREW Ø3 lg 60mm	32.92.60	3760347450629
MI- Screw Ø 4				
01	MI SCREW Ø4 lg 32	vis MI SCREW Ø4 lg 32mm	38.23.32	3760347450636
02	MI SCREW Ø4 lg 34	vis MI SCREW Ø4 lg 34mm	38.23.34	3760347450643
03	MI SCREW Ø4 lg 36	vis MI SCREW Ø4 lg 36mm	38.23.36	3760347450650
04	MI SCREW Ø4 lg 38	vis MI SCREW Ø4 lg 38mm	38.23.38	3760347450667
05	MI SCREW Ø4 lg 40	vis MI SCREW Ø4 lg 40mm	38.23.40	3760347450674
06	MI SCREW Ø4 lg 42	vis MI SCREW Ø4 lg 42mm	38.23.42	3760347450681
07	MI SCREW Ø4 lg 44	vis MI SCREW Ø4 lg 44mm	38.23.44	3760347450698
08	MI SCREW Ø4 lg 46	vis MI SCREW Ø4 lg 46mm	38.23.46	3760347450704
09	MI SCREW Ø4 lg 48	vis MI SCREW Ø4 lg 48mm	38.23.48	3760347450711
10	MI SCREW Ø4 lg 50	vis MI SCREW Ø4 lg 50mm	38.23.50	3760347450728
11	MI SCREW Ø4 lg 52	vis MI SCREW Ø4 lg 52mm	38.23.52	3760347450735
12	MI SCREW Ø4 lg 54	vis MI SCREW Ø4 lg 54mm	38.23.54	3760347450742
13	MI SCREW Ø4 lg 56	vis MI SCREW Ø4 lg 56mm	38.23.56	3760347450759
14	MI SCREW Ø4 lg 58	vis MI SCREW Ø4 lg 58mm	38.23.58	3760347450766
15	MI SCREW Ø4 lg 60	vis MI SCREW Ø4 lg 60mm	38.23.60	3760347450773
MY- Screw Ø 2.5				

01	MY SCREW Ø2.5 Lg 10	vis MY SCREW Ø2.5 Lg 10mm	38.88.10	3760347451343
02	MY SCREW Ø2.5 Lg 12	vis MY SCREW Ø2.5 Lg 12mm	38.88.12	3760347451350
03	MY SCREW Ø2.5 Lg 14	vis MY SCREW Ø2.5 Lg 14mm	38.88.14	3760347451367
04	MY SCREW Ø2.5 Lg 16	vis MY SCREW Ø2.5 Lg 16mm	38.88.16	3760347451374
05	MY SCREW Ø2.5 Lg 18	vis MY SCREW Ø2.5 Lg 18mm	38.88.18	3760347451381
06	MY SCREW Ø2.5 Lg 20	vis MY SCREW Ø2.5 Lg 20 mm	38.88.20	3760347451398
07	MY SCREW Ø2.5 Lg 22	vis MY SCREW Ø2.5 Lg 22mm	38.88.22	3760347451404
08	MY SCREW Ø2.5 Lg 24	vis MY SCREW Ø2.5 Lg 24 mm	38.88.24	3760347451411
09	MY SCREW Ø2.5 Lg 26	vis MY SCREW Ø2.5 Lg 26mm	38.88.26	3760347451428
10	MY SCREW Ø2.5 Lg 28	vis MY SCREW Ø2.5 Lg 28mm	38.88.28	3760347451435
11	MY SCREW Ø2.5 Lg 30	vis MY SCREW Ø2.5 Lg 30mm	38.88.30	3760347451442
12	MY SCREW Ø2.5 Lg 32	vis MY SCREW Ø2.5 Lg 32mm	38.88.32	3760347451459
13	MY SCREW Ø2.5 Lg 34	vis MY SCREW Ø2.5 Lg 34mm	38.88.34	3760347451466
MISS- Screw Ø 2				
01	MISS Ø2 Lg 13 mm	VIS MISS 13 mm	38.52.13	3760347450117
02	MISS Ø2 Lg 15 mm	VIS MISS 15 mm	38.52.15	3760347450124
03	MISS Ø2 Lg 17 mm	VIS MISS 17 mm	38.52.17	3760347450100
04	MISS Ø2 Lg 19 mm	VIS MISS 19 mm	38.52.19	3760347450131
05	MISS Ø2 Lg 22 mm	VIS MISS 22 mm	38.52.22	3760347450148
Varisation Staple				
01	Varisation Staple 26° 8 mm	Agrafe De Varisation angle 26° écartement 8 mm	14.55.04	3760347451046
02	Varisation Staple 26° 10 mm	Agrafe De Varisation angle 26° écartement 10 mm	14.55.03	3760347451732
03	Varisation Staple 90° 8 mm	Agrafe De Varisation angle 90° écartement 8 mm	14.55.02	3760347451749
04	Varisation Staple 90° 10 mm	Agrafe De Varisation angle 90° écartement 10 mm	14.55.01	3760347451756
Eagle Ø 4.6				
01	EAGLE Screw Ø4.6 Lg 20	vis EAGLE Ø4.6 Lg 20	38.98.20	3760347450780
02	EAGLE Screw Ø4.6 Lg 22	vis EAGLE Ø4.6 Lg 22	38.98.22	3760347450797
03	EAGLE Screw Ø4.6 Lg 24	vis EAGLE Ø4.6 Lg 24	38.98.24	3760347450803
04	EAGLE Screw Ø4.6 Lg 26	vis EAGLE Ø4.6 Lg 26	38.98.26	3760347450810
05	EAGLE Screw Ø4.6 Lg 28	vis EAGLE Ø4.6 Lg 28	38.98.28	3760347450827
06	EAGLE Screw Ø4.6 Lg 30	vis EAGLE Ø4.6 Lg 30	38.98.30	3760347450834
07	EAGLE Screw Ø4.6 Lg 32	vis EAGLE Ø4.6 Lg 32	38.98.32	3760347450841
08	EAGLE Screw Ø4.6 Lg 34	vis EAGLE Ø4.6 Lg 34	38.98.34	3760347450858
09	EAGLE Screw Ø4.6 Lg 36	vis EAGLE Ø4.6 Lg 36	38.98.36	3760347450865
10	EAGLE Screw Ø4.6 Lg 38	vis EAGLE Ø4.6 Lg 38	38.98.38	3760347450872
11	EAGLE Screw Ø4.6 Lg 40	vis EAGLE Ø4.6 Lg 40	38.98.40	3760347450889
12	EAGLE Screw Ø4.6 Lg 42	vis EAGLE Ø4.6 Lg 42	38.98.42	3760347450896
13	EAGLE Screw Ø4.6 Lg 44	vis EAGLE Ø4.6 Lg 44	38.98.44	3760347450902
14	EAGLE Screw Ø4.6 Lg 46	vis EAGLE Ø4.6 Lg 46	38.98.46	3760347450919

15	EAGLE Screw Ø4.6 Lg 48	vis EAGLE Ø4.6 Lg 48	38.98.48	3760347450926
16	EAGLE Screw Ø4.6 Lg 50	vis EAGLE Ø4.6 Lg 50	38.98.50	3760347450933
17	EAGLE Screw Ø4.6 Lg 52	vis EAGLE Ø4.6 Lg 52	38.98.52	3760347450940
18	EAGLE Screw Ø4.6 Lg 54	vis EAGLE Ø4.6 Lg 54	38.98.54	3760347450957
19	EAGLE Screw Ø4.6 Lg 56	vis EAGLE Ø4.6 Lg 56	38.98.56	3760347450964
20	EAGLE Screw Ø4.6 Lg 58	vis EAGLE Ø4.6 Lg 58	38.98.58	3760347450971
21	EAGLE Screw Ø4.6 Lg 60	vis EAGLE Ø4.6 Lg 60	38.98.60	3760347450988
Eagle Ø 7 16mm				
01	EAGLE Screw Ø7 16 MM Thread Lg 30	vis EAGLE Ø7 FILETAGE 16mm Lg 30	38.99.30A	3760347451473
02	EAGLE Screw Ø7 16 MM Thread Lg 35	vis EAGLE Ø7 FILETAGE 16mm Lg 35	38.99.35A	3760347451480
03	EAGLE Screw Ø7 16 MM Thread Lg 40	vis EAGLE Ø7 FILETAGE 16mm Lg 40	38.99.40A	3760347451497
04	EAGLE Screw Ø7 16 MM Thread Lg 45	vis EAGLE Ø7 FILETAGE 16mm Lg 45	38.99.45A	3760347451503
05	EAGLE Screw Ø7 16 MM Thread Lg 50	vis EAGLE Ø7 FILETAGE 16mm Lg 50	38.99.50A	3760347451510
06	EAGLE Screw Ø7 16 MM Thread Lg 55	vis EAGLE Ø7 FILETAGE 16mm Lg 55	38.99.55A	3760347451527
07	EAGLE Screw Ø7 16 MM Thread Lg 60	vis EAGLE Ø7 FILETAGE 16mm Lg 60	38.99.60A	3760347451534
08	EAGLE Screw Ø7 16 MM Thread Lg 65	vis EAGLE Ø7 FILETAGE 16mm Lg 65	38.99.65A	3760347451541
09	EAGLE Screw Ø7 16 MM Thread Lg 70	vis EAGLE Ø7 FILETAGE 16mm Lg 70	38.99.70A	3760347451558
10	EAGLE Screw Ø7 16 MM Thread Lg 75	vis EAGLE Ø7 FILETAGE 16mm Lg 75	38.99.75A	3760347451565
11	EAGLE Screw Ø7 16 MM Thread Lg 80	vis EAGLE Ø7 FILETAGE 16mm Lg 80	38.99.80A	3760347451572
12	EAGLE Screw Ø7 16 MM Thread Lg 85	vis EAGLE Ø7 FILETAGE 16mm Lg 85	38.99.85A	3760347451589
13	EAGLE Screw Ø7 16 MM Thread Lg 90	vis EAGLE Ø7 FILETAGE 16mm Lg 90	38.99.90A	3760347451596
Eagle Ø 7 22 mm				
01	EAGLE Screw Ø7 22MM Thread Lg55	vis EAGLE Ø7 FILETAGE 22mm Lg55	38.99.55B	3760347451602
02	EAGLE Screw Ø7 22MM Thread Lg60	vis EAGLE Ø7 FILETAGE 22mm Lg60	38.99.60B	3760347451619
03	EAGLE Screw Ø7 22MM Thread Lg65	vis EAGLE Ø7 FILETAGE 22mm Lg65	38.99.65B	3760347451626
04	EAGLE Screw Ø7 22MM Thread Lg70	vis EAGLE Ø7 FILETAGE 22mm Lg70	38.99.70B	3760347451633
05	EAGLE Screw Ø7 22MM Thread Lg75	vis EAGLE Ø7 FILETAGE 22mm Lg75	38.99.75B	3760347451640
06	EAGLE Screw Ø7 22MM Thread Lg80	vis EAGLE Ø7 FILETAGE 22mm Lg80	38.99.80B	3760347451657
07	EAGLE Screw Ø7 22MM Thread Lg85	vis EAGLE Ø7 FILETAGE 22mm Lg85	38.99.85B	3760347451664
08	EAGLE Screw Ø7 22MM Thread Lg90	vis EAGLE Ø7 FILETAGE 22mm Lg90	38.99.90B	3760347451671
Eagle Ø 7 28 mm				
01	EAGLE Screw Ø7 28MM Thread Lg70	vis EAGLE Ø7 FILETAGE 28mm Lg 70	38.99.70C	3760347451688
02	EAGLE Screw Ø7 28MM Thread Lg75	vis EAGLE Ø7 FILETAGE 28mm Lg 75	38.99.75C	3760347451695
03	EAGLE Screw Ø7 28MM Thread Lg80	vis EAGLE Ø7 FILETAGE 28mm Lg 80	38.99.80C	3760347451701
04	EAGLE Screw Ø7 28MM Thread Lg85	vis EAGLE Ø7 FILETAGE 28mm Lg 85	38.99.85C	3760347451718
05	EAGLE Screw Ø7 28MM Thread Lg90	vis EAGLE Ø7 FILETAGE 28mm Lg 90	38.99.90C	3760347451725
Arthrostab Ø 4.6				
01	ARTHROSTAB Screw Ø4.6 Lg 20mm	vis ARTHROSTAB Ø4.6 Lg 20mm	38.21.20	3760347450995
02	ARTHROSTAB Screw Ø4.6 Lg 22mm	vis ARTHROSTAB Ø4.6 Lg 22mm	38.21.22	3760347451008
03	ARTHROSTAB Screw Ø4.6 Lg 24mm	vis ARTHROSTAB Ø4.6 Lg 24mm	38.21.24	3760347451015
04	ARTHROSTAB Screw Ø4.6 Lg 26mm	vis ARTHROSTAB Ø4.6 Lg 26mm	38.21.26	3760347451022
05	ARTHROSTAB Screw Ø4.6 Lg 28mm	vis ARTHROSTAB Ø4.6 Lg 28mm	38.21.28	3760347451039

06	ARTHROSTAB Screw Ø4.6 Lg 30mm	vis ARTHROSTAB Ø4.6 Lg 30mm	38.21.30	3760347451053
07	ARTHROSTAB Screw Ø4.6 Lg 32mm	vis ARTHROSTAB Ø4.6 Lg 32mm	38.21.32	3760347451060
08	ARTHROSTAB Screw Ø4.6 Lg 34mm	vis ARTHROSTAB Ø4.6 Lg 34mm	38.21.34	3760347451077
09	ARTHROSTAB Screw Ø4.6 Lg 36mm	vis ARTHROSTAB Ø4.6 Lg 36mm	38.21.36	3760347451084
10	ARTHROSTAB Screw Ø4.6 Lg 38mm	vis ARTHROSTAB Ø4.6 Lg 38mm	38.21.38	3760347451091
11	ARTHROSTAB Screw Ø4.6 Lg 40mm	vis ARTHROSTAB Ø4.6 Lg 40mm	38.21.40	3760347451107
12	ARTHROSTAB Screw Ø4.6 Lg 42mm	vis ARTHROSTAB Ø4.6 Lg 42mm	38.21.42	3760347451114
13	ARTHROSTAB Screw Ø4.6 Lg 44mm	vis ARTHROSTAB Ø4.6 Lg 44mm	38.21.44	3760347451121
14	ARTHROSTAB Screw Ø4.6 Lg 46mm	vis ARTHROSTAB Ø4.6 Lg 46mm	38.21.46	3760347451138
15	ARTHROSTAB Screw Ø4.6 Lg 48mm	vis ARTHROSTAB Ø4.6 Lg 48mm	38.21.48	3760347451145
16	ARTHROSTAB Screw Ø4.6 Lg 50mm	vis ARTHROSTAB Ø4.6 Lg 50mm	38.21.50	3760347451152
17	ARTHROSTAB Screw Ø4.6 Lg 52mm	vis ARTHROSTAB Ø4.6 Lg 52mm	38.21.52	3760347451169
18	ARTHROSTAB Screw Ø4.6 Lg 54mm	vis ARTHROSTAB Ø4.6 Lg 54mm	38.21.54	3760347451176
19	ARTHROSTAB Screw Ø4.6 Lg 56mm	vis ARTHROSTAB Ø4.6 Lg 56mm	38.21.56	3760347451183
20	ARTHROSTAB Screw Ø4.6 Lg 58mm	vis ARTHROSTAB Ø4.6 Lg 58mm	38.21.58	3760347451190
21	ARTHROSTAB Screw Ø4.6 Lg 60mm	vis ARTHROSTAB Ø4.6 Lg 60mm	38.21.60	3760347451206
Arthrostab Ø 7				
01	ARTHROSTAB Screw Ø7 Lg 30	vis ARTHROSTAB Ø7 Lg30 mm	38.22.30	3760347451213
02	ARTHROSTAB Screw Ø7 Lg 35	vis ARTHROSTAB Ø7 Lg35 mm	38.22.35	3760347451220
03	ARTHROSTAB Screw Ø7 Lg 40	vis ARTHROSTAB Ø7 Lg40 mm	38.22.40	3760347451237
04	ARTHROSTAB Screw Ø7 Lg 45	vis ARTHROSTAB Ø7 Lg45 mm	38.22.45	3760347451244
05	ARTHROSTAB Screw Ø7 Lg 50	vis ARTHROSTAB Ø7 Lg50 mm	38.22.50	3760347451251
06	ARTHROSTAB Screw Ø7 Lg 55	vis ARTHROSTAB Ø7 Lg55 mm	38.22.55	3760347451268
07	ARTHROSTAB Screw Ø7 Lg 60	vis ARTHROSTAB Ø7 Lg60 mm	38.22.60	3760347451275
08	ARTHROSTAB Screw Ø7 Lg 65	vis ARTHROSTAB Ø7 Lg65 mm	38.22.65	3760347451282
09	ARTHROSTAB Screw Ø7 Lg 70	vis ARTHROSTAB Ø7 Lg70 mm	38.22.70	3760347451299
10	ARTHROSTAB Screw Ø7 Lg 75	vis ARTHROSTAB Ø7 Lg75 mm	38.22.75	3760347451305
11	ARTHROSTAB Screw Ø7 Lg 80	vis ARTHROSTAB Ø7 Lg80 mm	38.22.80	3760347451312
12	ARTHROSTAB Screw Ø7 Lg 85	vis ARTHROSTAB Ø7 Lg85 mm	38.22.85	3760347451329
13	ARTHROSTAB Screw Ø7 Lg 90	vis ARTHROSTAB Ø7 Lg90 mm	38.22.90	3760347451336
PIN (K Wire) 1 Tip				
01	PIN K-WIRE Ø1 LG 70	Broche Ø1 Lg 70	14.63.01	3760347451794
02	PIN K-WIRE Ø1,5 LG 150 1 TIP	Broche Ø1,5 Lg 150 1 Pointe Trocart	14.63.44	3760347451770
03	PIN K-WIRE THREADED Ø2,2 LG 200 1 TIP	Broche Filetée Ø2,2 Lg 200 1 Pointe	14.63.45	3760347451787
04	PIN K-WIRE Ø 2.2 Lg 200 1 TIP	Broche 1 Pointe Ø 2.2 Lg 200	14.63.10	3760347451855
05	PIN K-WIRE Ø1 LG 150 1 TIP	Broche Ø1 Lg 150 1 Pointe	14.63.48	3760347451763
06	PIN K-WIRE Ø1,2 LG 100 1 TIP	Broche 1 Pointe Ø 1.2 Lg 100	14.63.42	3760347452180
07	PIN K-WIRE Ø1,2 LG 150 1 TIP	Broche 1 Pointe Ø 1.2 Lg 150	14.63.35	3760347452197
08	PIN K-WIRE Ø1.8 LG 150 1 TIP	Broche 1 Pointe Ø 1.8 Lg 150	14.63.05	3760347452203
09	PIN K-WIRE Ø2,0 LG 120 1 TIP	Broche 1 Pointe Ø 2 Lg 120	14.63.43	3760347452210
10	PIN K-WIRE Ø2.0 LG 200 1 TIP	Broche 1 Pointe Ø 2 Lg 200	14.63.08	3760347452227
11	PIN K-WIRE Ø2.4 LG 200 1 TIP	Broche 1 Pointe Ø 2.4 Lg 200	14.63.47	3760347452234

12	PIN K-WIRE Ø2.4 LG 230 1 TIP	Broche 1 Pointe Ø 2.4 Lg 230	14.63.46	3760347452241
13	PIN K-WIRE Ø2.5 LG 150 1 TIP	Broche 1 Pointe Ø 2.5 Lg 150	14.63.07	3760347452258
14	PIN K-WIRE Ø3 LG 200 1 TIP	Broche 1 Pointe Ø 3 Lg 200	14.63.11	3760347452265
15	PIN K-WIRE THREADED Ø 1.5 LG 150	Broche Filetée Ø1.5 Lg 150	14.63.02	3760347452272
PIN (K Wire) 2 Tip				
01	PIN K-WIRE Ø 0.8 LG 70	Broche Double Pointe Ø 0.8 Lg 70 MM	14.63.41	3760347452142
02	PIN K-WIRE Ø 0.8 LG 80 2 TIP	Broche Double Pointe Ø0.8 Lg 80 MM	14.63.36	3760347452289
03	PIN K-WIRE Ø 0.8 LG 200 2 TIP	Broche Double Pointe Ø 0.8 Lg 200 MM	14.63.37	3760347452296
04	PIN K-WIRE Ø1.0 LG 105 2 TIP	Broche Double Pointe Ø 1.0 Lg 105 MM	14.63.31	3760347452302
05	PIN K-WIRE Ø1.0 LG 200 2 TIP	Broche Double Pointe Ø 1.0 Lg 200 MM	14.63.38	3760347452319
06	PIN K-WIRE Ø1.2 LG 150 2 TIP	Broche Double Pointe Ø 1.2 Lg 150 MM	14.63.32	3760347452326
07	PIN K-WIRE Ø1.2 LG 200 2 TIP	Broche Double Pointe Ø 1.2 Lg 200 MM	14.63.39	3760347452333
08	PIN K-WIRE Ø1.5 LG 300 2 TIP	Broche Double Pointe Ø 1.5 Lg 300 MM	14.63.40	3760347452340
09	PIN K-WIRE Ø1.0 LG 100 2 TIP	Broche Double Pointe Ø 1 Lg 100 MM	14.63.34	3760347452357
Pin with Ball				
01	PIN WITH BALL Ø1	Broche À Bille Ø 1	38.63.13/18	3760347451800
02	PIN WITH BALL Ø1,2	Broche À Bille Ø 1.2	38.63.14/18	3760347451817
03	PIN WITH BALL Ø1,5	Broche À Bille Ø 1.5	38.63.15/19	3760347451824
04	PIN WITH BALL Ø1,8	Broche À Bille Ø 1.8	38.63.16/20	3760347451831
05	PIN WITH BALL Ø2.0	Broche À Bille Ø 2.0	38.63.17/20	3760347451848

Classe de risque du dispositif médical : Classe IIb selon la règle 8 de l'annexe VIII du règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017: « Règle 8 : Tous les dispositifs implantables et les dispositifs invasifs à long terme de type chirurgical font partie de la classe II b ».

Medical device risk class : Class IIb according to Rule 8 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of the 5 April 2017 : "Rule 8: All implantable devices and long-term surgically invasive devices are classified as class IIb".

Les dispositifs couverts par la présente déclaration UE sont conformes à l'annexe IX du Règlement (UE) 2017/745. La documentation technique est tenue à disposition.

The devices covered by the present EU declaration is in conformity with Annex IX of Regulation (EU) 2017/745. The technical documentation is kept available.

Références des normes harmonisées et/ou autres spécifications techniques appliquées :

References of harmonized standards and/or other technical specifications applied:

Standards	Title
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2023	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11137-2:2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2 :2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ISO 14602 :2011	Non-active surgical implants - Implants for osteosynthesis - Particular requirements
ISO 14630 : 2009	Non-active surgical implants - General requirements

Organisme notifié : HTCert (RDM 745 et directive 93/42/CEE)

Numéro d'identification UE : 2803

Procédure d'évaluation de la conformité effectuée : Système d'assurance qualité complet

Certificat CE N° : 3585C04210501

Notified Body: HTCert (MDR 745 & Directive 93/42/EEC)

EU identification number: 2803

Conformity assessment procedure performed: Full Quality Assurance System

EC certificate N°: 3585C04210501

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Jean-Pierre PY
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