

Déclaration de
conformité



Declaration of
conformity

Dispositif médical <i>Medical device</i>	Classe <i>Class</i>	Référence <i>Reference</i>
Cupule CAPITOLE double mobilité à cimenter CAPITOLE Cemented Dual Mobility Cup	III	H51 Cxx

Nous, société EVOLUTIS, située à, Avenue de la libération 42720 Briennon, France

Déclarons que les dispositifs médicaux définis ci-dessus et détaillés dans l'addendum ci-joint (2 pages) sont conformes aux Directives Européennes 93/42/CEE (annexe II – Section 4) 2005/50/CEE et 2007/47/CEE sur les dispositifs médicaux.

BSI (NL), organisme notifié N° 2797, a délivré le certificat **CE 644021**.

We, EVOLUTIS company, located Avenue de la libération 42720 Briennon France

Hereby declare that the medical devices defined above and detailed in the enclosed addendum (2 pages) are complying with the European Directive 93/42/EEC (appendix II – Section 4) 2005/50/EEC and 2007/47/EEC concerning medical devices.

*BSI (NL), notified body N° 2797, issued certificate **CE 644021**.*

BRIENNON, le 27/08/2019

Date de validité : 26/05/2024

Date of expiration

Gérard PÉLISSON

Directeur Qualité / Affaires Règlementaires
Quality and Regulatory Affairs Manager


E v o l u t i s

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*Annexe à la déclaration de conformité
 Declaration of conformity Addendum*

Dispositif médical Medical device	Classe Class	Référence Reference
Cupule CAPITOLE double mobilité à cimenter CAPITOLE Cemented Dual Mobility Cup	III	H51 Cxx

Reference	Désignation 1 - FR	Désignation 2 - FR	Description 1 - UK	Description 2 - UK	Class
H51 Co45	Cupule CAPITOLE C à cimenter	double mobilité Ø 45	CAPITOLE C Cemented cup	dual mobility Ø 45	C3
H51 Co47	Cupule CAPITOLE C à cimenter	double mobilité Ø 47	CAPITOLE C Cemented cup	dual mobility Ø 47	C3
H51 Co49	Cupule CAPITOLE C à cimenter	double mobilité Ø 49	CAPITOLE C Cemented cup	dual mobility Ø 49	C3
H51 Co51	Cupule CAPITOLE C à cimenter	double mobilité Ø 51	CAPITOLE C Cemented cup	dual mobility Ø 51	C3
H51 Co53	Cupule CAPITOLE C à cimenter	double mobilité Ø 53	CAPITOLE C Cemented cup	dual mobility Ø 53	C3
H51 Co55	Cupule CAPITOLE C à cimenter	double mobilité Ø 55	CAPITOLE C Cemented cup	dual mobility Ø 55	C3
H51 Co57	Cupule CAPITOLE C à cimenter	double mobilité Ø 57	CAPITOLE C Cemented cup	dual mobility Ø 57	C3
H51 Co59	Cupule CAPITOLE C à cimenter	double mobilité Ø 59	CAPITOLE C Cemented cup	dual mobility Ø 59	C3
H51 Co61	Cupule CAPITOLE C à cimenter	double mobilité Ø 61	CAPITOLE C Cemented cup	dual mobility Ø 61	C3
H51 M2245	Insert mobile Ø44&45 tête 22.2		Dual Mobility mobile insert	Ø45-44 for head 22.2	C3
H51 M2247	Insert mobile Ø46&47 tête 22.2		Dual Mobility mobile insert	Ø47-46 for head 22.2	C3
H51 M2249	Insert mobile Ø48&49 tête 22.2		Dual Mobility mobile insert	Ø49-48 for head 22.2	C3
H51 M2251	Insert mobile Ø50&51 tête 22.2		Dual Mobility mobile insert	Ø51-50 for head 22.2	C3
H51 M2253	Insert mobile Ø52&53 tête 22.2		Dual Mobility mobile insert	Ø53-52 for head 22.2	C3
H51 M2255	Insert mobile Ø54&55 tête 22.2		Dual Mobility mobile insert	Ø55-54 for head 22.2	C3
H51 M2257	Insert mobile Ø56&57 tête 22.2		Dual Mobility mobile insert	Ø57-56 for head 22.2	C3
H51 M2259	Insert mobile Ø58&59 tête 22.2		Dual Mobility mobile insert	Ø59-58 for head 22.2	C3
H51 M2261	Insert mobile Ø60&61 tête 22.2		Dual Mobility mobile insert	Ø61-60 for head 22.2	C3
H51 M2263	Insert mobile Ø62&63 tête 22.2		Dual Mobility mobile insert	Ø63-62 for head 22.2	C3
H51 M2265	Insert mobile Ø64&65&66 / 22.2		Dual Mobility mobile insert	Ø64-65-66 for head 22.2	C3
H51 M2847	Insert mobile Ø46&47 tête 28		Dual Mobility mobile insert	Ø47-46 for head 28	C3

H51 M2849	Insert mobile Ø48&49 tête 28		Dual Mobility mobile insert	Ø49-48 for head 28	C3
H51 M2851	Insert mobile Ø50&51 tête 28		Dual Mobility mobile insert	Ø51-50 for head 28	C3
H51 M2853	Insert mobile Ø52&53 tête 28		Dual Mobility mobile insert	Ø53-52 for head 28	C3
H51 M2855	Insert mobile Ø54&55 tête 28		Dual Mobility mobile insert	Ø55-54 for head 28	C3
H51 M2857	Insert mobile Ø56&57 tête 28		Dual Mobility mobile insert	Ø57-56 for head 28	C3
H51 M2859	Insert mobile Ø58&59 tête 28		Dual Mobility mobile insert	Ø59-58 for head 28	C3
H51 M2861	insert mobile Ø60&61 tête 28		Dual Mobility mobile insert	Ø61-60 for head 28	C3
H13 050	Fond de cotyle Ø50	Extérieur 54, intérieur 50	Acetabular plate Ø50 inside	Ø54 external, Ø50 inside	C2b
H13 054	Fond de cotyle Ø54	Extérieur 58, intérieur 54	Acetabular plate Ø54 inside	Ø58 external, Ø54 inside	C2b
H13 058	Fond de cotyle Ø58	Extérieur 62, intérieur 58	Acetabular plate Ø58 inside	Ø62 external, Ø58 inside	C2b
H13 062	Fond de cotyle Ø62	Extérieur 66, intérieur 62	Acetabular plate Ø62 inside	Ø66 external, Ø62 inside	C2b
H16 S5035	Vis corticale inox Ø 5 lg 35mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 35 mm	Self-tapping and sterile	C2b
H16 S5040	Vis corticale inox Ø 5 lg 40mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 40 mm	Self tapping and sterile	C2b
H16 S5045	Vis corticale inox Ø 5 lg 45mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 45mm	Self tapping and sterile	C2b
H16 S5050	Vis corticale inox Ø 5 lg 50mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 50mm	Self tapping and sterile	C2b
H16 S5055	Vis corticale inox Ø 5 lg 55mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 55 mm	Self tapping and sterile	C2b
H16 S5060	Vis corticale inox Ø 5 lg 60mm	autotaraudeuse stérile	SS cortical screw Ø 5 lg 60mm	Self tapping and sterile	C2b