

Déclaration de  
conformité



Declaration of  
conformity

Dispositif médical <i>Medical device</i>	Classe Class	Référence Reference
Vis Corticales / Vis Spongieuses Cortical Screws / Cancellous Screws	IIb	T43 HAxxxx T43 HBxxxx

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 – à l'exclusion de la Section 4), 2005/50/CEE et 2007/47/CEE sur les dispositifs médicaux.  
BSI (NL), organisme notifié N° 2797, a délivré le certificat **CE 643976**.

*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 – excluding Section 4), 2005/50/EEC and 2007/47/EEC concerning medical devices.  
BSI (NL), notified body N° 2797, issued certificate **CE 643976**.*

BRIENNON, le 25/03/2019

Date de validité : 25/10/2020  
*Date of expiration*

Gérard PÉLISSON  
Responsable qualité  
*Quality manager*

**Evolutis**  
C R E A T E U R F A B R I C A N T  
Avenue de la libération - 42720 BRIENNON  
Tél. : 04.77.60.79.99 Fax : 04.77.60.79.90

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

Dispositif médical Medical device		Classe Class	Référence Reference
Vis Corticales / Vis Spongieuses Cortical Screws / Cancellous Screws		IIb	T43 HAxxxx T43 HBxxxx

Reference	Designation 1 - FR	Designation 2 - FR	Description 1 - UK	Description 2 - UK	Class
T43 HA3514	Vis corticale HA autotaraudante	Ø 3,5 - Lg 14 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 14 mm SS sterile	IIb
T43 HA3516	Vis corticale HA autotaraudante	Ø 3,5 - Lg 16 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 16 mm SS sterile	IIb
T43 HA3518	Vis corticale HA autotaraudante	Ø 3,5 - Lg 18 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 18 mm SS sterile	IIb
T43 HA3520	Vis corticale HA autotaraudante	Ø 3,5 - Lg 20 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 20 mm SS sterile	IIb
T43 HA3522	Vis corticale HA autotaraudante	Ø 3,5 - Lg 22 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 22 mm SS sterile	IIb
T43 HA3525	Vis corticale HA autotaraudante	Ø 3,5 - Lg 25 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 25 mm SS sterile	IIb
T43 HA3530	Vis corticale HA autotaraudante	Ø 3,5 - Lg 30 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 30 mm SS sterile	IIb
T43 HA3535	Vis corticale HA autotaraudante	Ø 3,5 - Lg 35 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 35 mm SS sterile	IIb
T43 HA3540	Vis corticale HA autotaraudante	Ø 3,5 - Lg 40 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 40 mm SS sterile	IIb
T43 HA3545	Vis corticale HA autotaraudante	Ø 3,5 - Lg 45 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 45 mm SS sterile	IIb
T43 HA3550	Vis corticale HA autotaraudante	Ø 3,5 - Lg 50 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 50 mm SS sterile	IIb
T43 HA3555	Vis corticale HA autotaraudante	Ø 3,5 - Lg 55 mm INOX STERILE	Cortical screw HA self-tapping	Ø3,5 - Lg 55 mm SS sterile	IIb
T43 HA4516	Vis corticale HA autotaraudante	Ø 4,5 - Lg 16 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 16 mm SS sterile	IIb
T43 HA4518	Vis corticale HA autotaraudante	Ø 4,5 - Lg 18 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 18 mm SS sterile	IIb
T43 HA4520	Vis corticale HA autotaraudante	Ø 4,5 - Lg 20 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 20 mm SS sterile	IIb



T43 HA4522	Vis corticale HA autotaraudante	Ø 4,5 - Lg 22 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 22 mm SS sterile	ilb
T43 HA4525	Vis corticale HA autotaraudante	Ø 4,5 - Lg 25 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 25 mm SS sterile	ilb
T43 HA4530	Vis corticale HA autotaraudante	Ø 4,5 - Lg 30 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 30 mm SS sterile	ilb
T43 HA4535	Vis corticale HA autotaraudante	Ø 4,5 - Lg 35 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 35 mm SS sterile	ilb
T43 HA4540	Vis corticale HA autotaraudante	Ø 4,5 - Lg 40 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 40 mm SS sterile	ilb
T43 HA4545	Vis corticale HA autotaraudante	Ø 4,5 - Lg 45 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 45 mm SS sterile	ilb
T43 HA4550	Vis corticale HA autotaraudante	Ø 4,5 - Lg 50 mm INOX STERILE	Cortical screw HA self-tapping	Ø4,5 - Lg 50 mm SS sterile	ilb
T43 HB4012	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 12 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 12 mm SS sterile	ilb
T43 HB4014	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 14 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 14 mm SS sterile	ilb
T43 HB4016	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 16 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 16 mm SS sterile	ilb
T43 HB4018	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 18 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 18 mm SS sterile	ilb
T43 HB4020	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 20 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 20 mm SS sterile	ilb
T43 HB4022	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 22 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 22 mm SS sterile	ilb
T43 HB4025	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 25 mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 25 mm SS sterile	ilb
T43 HB4030	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 30mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 30 mm SS sterile	ilb
T43 HB4035	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 35mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 35 mm SS sterile	ilb
T43 HB4040	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 40mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 40 mm SS sterile	ilb
T43 HB4045	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 45mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 45 mm SS sterile	ilb
T43 HB4050	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 50mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 50 mm SS sterile	ilb
T43 HB4055	Vis spongieuse HB ent. filetée	Ø 4,0 - Lg 55mm INOX STERILE	Cancellous screw HB full thread	Ø4,0 - Lg 55 mm SS sterile	ilb