

**ADSM**

7b rue Lavoisier

69680 Chassieu - FRANCE

Tel : +33 (0)4 28 71 03 10 // Fax : +33 (0)4 28 71 03 20

[office@synchromedical.com](mailto:office@synchromedical.com)


Single registration number : FR-MF-000001222.


Chassieu, on 2023/12/05

**EC CONFORMITY DECLARATION**


*TIGER22, TIGER29, TIGER29 FLANGE, TIGER35, TIGER35 FLANGE, TIGER45,  
EXRAY30 & EXRAY35*


ADSM, represented by Luigi BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices comply with all the provisions of Directive 93/42/CEE dated June, 14th 1993, modified by the Directive 2007/47/CEE dated September, 5<sup>th</sup> 2007 and with provisions from the Public Health Code, section 5, book number II, 1<sup>st</sup> Title (article R665-1 et al., if applicable) :



TIGER 22							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV2211	Self-compressive cannulated screw	2,2	11	03701091000982	IIb	Appendix : VIII Rule : 8
	HV2213	Self-compressive cannulated screw		13	03701091000999		
	HV2215	Self-compressive cannulated screw		15	03701091001002		
	HV2217	Self-compressive cannulated screw		17	03701091001019		
	HV2219	Self-compressive cannulated screw		19	03701091001026		
	HV2221	Self-compressive cannulated screw		21	03701091001033		
	HV2223	Self-compressive cannulated screw		23	03701091001040		
	HV2225	Self-compressive cannulated screw		25	03701091001057		
	HV2227	Self-compressive cannulated screw		27	03701091001064		
	HV2229	Self-compressive cannulated screw		29	03701091001071		
	HV2231	Self-compressive cannulated screw		31	03701091001088		
	HV2233	Self-compressive cannulated screw		33	03701091001095		
	HV2235	Self-compressive cannulated screw		35	03701091001101		
	HV2237	Self-compressive cannulated screw		37	03701091001118		
	HV2239	Self-compressive cannulated screw		39	03701091001125		
	HV2241	Self-compressive cannulated screw		41	03701091001132		
HV2243	Self-compressive cannulated screw	43	03701091001149				
HV2245	Self-compressive cannulated screw	45	03701091001156				

TIGER 29 / TIGER 29 FLANGE							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV2911	Self-compressive cannulated screw	2,9	11	03701091001163	IIb	Appendix : VIII Rule : 8
	HV2913	Self-compressive cannulated screw		13	03701091001170		
	HV2915	Self-compressive cannulated screw		15	03701091001187		
	HV2917	Self-compressive cannulated screw		17	03701091001194		
	HV2919	Self-compressive cannulated screw		19	03701091001200		

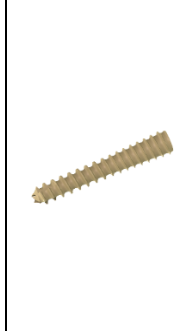
TIGER 29 / TIGER 29 FLANGE							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV2921	Self-compressive cannulated screw		21	03701091001217		
	HV2923	Self-compressive cannulated screw		23	03701091001224		
	HV2925	Self-compressive cannulated screw		25	03701091001231		
	HV2927	Self-compressive cannulated screw		27	03701091001248		
	HV2929	Self-compressive cannulated screw		29	03701091001255		
	HV2931	Self-compressive cannulated screw		31	03701091001262		
	HV2933	Self-compressive cannulated screw		33	03701091001279		
	HV2935	Self-compressive cannulated screw		35	03701091001286		
	HV2937	Self-compressive cannulated screw		37	03701091001293		
	HV2939	Self-compressive cannulated screw		39	03701091001309		
	HV2941	Self-compressive cannulated screw		41	03701091001316		
	HV2943	Self-compressive cannulated screw		43	03701091001323		
	HV2945	Self-compressive cannulated screw		45	03701091001330		
	HV3F2919	30° Flanged Self-compressive cannulated screw	2,9	19	03701091005789	IIb	Appendix : VIII Rule : 8
	HV3F2921	30° Flanged Self-compressive cannulated screw		21	03701091005796		
	HV3F2923	30° Flanged Self-compressive cannulated screw		23	03701091005802		
	HV3F2925	30° Flanged Self-compressive cannulated screw		25	03701091005819		
	HV3F2927	30° Flanged Self-compressive cannulated screw		27	03701091005826		
	HV3F2929	30° Flanged Self-compressive cannulated screw		29	03701091005833		
	HV3F2931	30° Flanged Self-compressive cannulated screw		31	03701091005840		
	HV3F2933	30° Flanged Self-compressive cannulated screw		33	03701091005857		

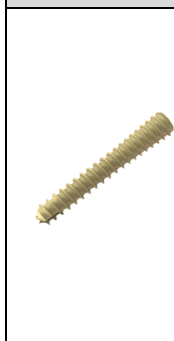
TIGER 35 / TIGER 35 FLANGE							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV3523	Self-compressive cannulated screw	3,5	23	03701091005598	IIb	Appendix : VIII Rule : 8
	HV3525	Self-compressive cannulated screw		25	03701091005581		
	HV3527	Self-compressive cannulated screw		27	03701091005604		
	HV3529	Self-compressive cannulated screw		29	03701091005611		
	HV3531	Self-compressive cannulated screw		31	03701091005628		
	HV3533	Self-compressive cannulated screw		33	03701091005635		
	HV3535	Self-compressive cannulated screw		35	03701091005642		
	HV3537	Self-compressive cannulated screw		37	03701091005659		
	HV3539	Self-compressive cannulated screw		39	03701091005666		
	HV3541	Self-compressive cannulated screw		41	03701091005673		
	HV3543	Self-compressive cannulated screw		43	03701091005680		
	HV3545	Self-compressive cannulated screw		45	03701091005697		
	HV3547	Self-compressive cannulated screw		47	03701091005703		
	HV3549	Self-compressive cannulated screw		49	03701091005710		
	HV3551	Self-compressive cannulated screw		51	03701091005727		
	HV3553	Self-compressive cannulated screw		53	03701091005734		
	HV3555	Self-compressive cannulated screw		55	03701091005741		
	HV3557	Self-compressive cannulated screw		57	03701091005758		
	HV3559	Self-compressive cannulated screw		59	03701091005765		
	HV3561	Self-compressive cannulated screw		61	03701091005772		
	HV6F3533	60° Flanged Self-compressive cannulated screw	3,5	33	03701091005864	IIb	Appendix : VIII Rule : 8
	HV6F3535	60° Flanged Self-compressive cannulated screw		35	03701091005871		

TIGER 35 / TIGER 35 FLANGE							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV6F3537	60° Flanged Self-compressive cannulated screw		37	03701091005888		
	HV6F3539	60° Flanged Self-compressive cannulated screw		39	03701091005895		
	HV6F3541	60° Flanged Self-compressive cannulated screw		41	03701091005901		
	HV6F3543	60° Flanged Self-compressive cannulated screw		43	03701091005918		
	HV6F3545	60° Flanged Self-compressive cannulated screw		45	03701091005925		
	HV6F3547	60° Flanged Self-compressive cannulated screw		47	03701091005932		
	HV6F3549	60° Flanged Self-compressive cannulated screw		49	03701091005949		
	HV6F3551	60° Flanged Self-compressive cannulated screw		51	03701091005956		
	HV6F3553	60° Flanged Self-compressive cannulated screw		53	03701091005963		
	HV6F3555	60° Flanged Self-compressive cannulated screw		55	03701091005970		

TIGER 45							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV4525	Self-compressive cannulated screw	4,5	25	03701091001774	IIb	Appendix : VIII Rule : 8
	HV4527	Self-compressive cannulated screw		27	03701091001781		
	HV4529	Self-compressive cannulated screw		29	03701091001798		
	HV4531	Self-compressive cannulated screw		31	03701091001804		
	HV4533	Self-compressive cannulated screw		33	03701091001811		
	HV4535	Self-compressive cannulated screw		35	03701091001828		
	HV4537	Self-compressive cannulated screw		37	03701091001835		
	HV4539	Self-compressive cannulated screw		39	03701091001842		
	HV4541	Self-compressive cannulated screw		41	03701091001859		
	HV4543	Self-compressive cannulated screw		43	03701091001866		
	HV4545	Self-compressive cannulated screw		45	03701091001873		
	HV4547	Self-compressive cannulated screw		47	03701091001880		
	HV4549	Self-compressive cannulated screw		49	03701091001897		
	HV4551	Self-compressive cannulated screw		51	03701091001903		
	HV4553	Self-compressive cannulated screw		53	03701091001910		
	HV4555	Self-compressive cannulated screw		55	03701091001927		
	HV4557	Self-compressive cannulated screw		57	03701091001934		
	HV4559	Self-compressive cannulated screw		59	03701091001941		
HV4561	Self-compressive cannulated screw	61	03701091001958				
	CT4525	Self-compressive, continuous thread, cannulated screw	4,0	25	03701091001965		
	CT4527	Self-compressive, continuous thread, cannulated screw		27	03701091001972		
	CT4529	Self-compressive, continuous thread, cannulated screw		29	03701091001989		
	CT4531	Self-compressive, continuous thread, cannulated screw		31	3701091001996		
	CT4533	Self-compressive, continuous thread, cannulated screw		33	03701091002009		
	CT4535	Self-compressive, continuous thread, cannulated screw		35	03701091002016		
	CT4537	Self-compressive, continuous thread, cannulated screw		37	03701091002023		

TIGER 45							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	CT4539	Self-compressive, continuous thread, cannulated screw		39	03701091002030		
	CT4541	Self-compressive, continuous thread, cannulated screw		41	03701091002047		
	CT4543	Self-compressive, continuous thread, cannulated screw		43	03701091002054		
	CT4545	Self-compressive, continuous thread, cannulated screw		45	03701091002061		
	CT4547	Self-compressive, continuous thread, cannulated screw		47	03701091002078		
	CT4549	Self-compressive, continuous thread, cannulated screw		49	03701091002085		
	CT4551	Self-compressive, continuous thread, cannulated screw		51	03701091002092		
	CT4553	Self-compressive, continuous thread, cannulated screw		53	03701091002108		
	CT4555	Self-compressive, continuous thread, cannulated screw		55	03701091002115		
	CT4557	Self-compressive, continuous thread, cannulated screw		57	03701091002122		
	CT4559	Self-compressive, continuous thread, cannulated screw		59	03701091002139		
	CT4561	Self-compressive, continuous thread, cannulated screw		61	03701091002146		

EXRAY 30							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HVP3011	Self-compressive cannulated screw	3,0	11	03701091001347	IIb	Appendix : VIII Rule : 8
	HVP3013	Self-compressive cannulated screw		13	03701091001354		
	HVP3015	Self-compressive cannulated screw		15	03701091001361		
	HVP3017	Self-compressive cannulated screw		17	03701091001378		
	HVP3019	Self-compressive cannulated screw		19	03701091001385		
	HVP3021	Self-compressive cannulated screw		21	03701091001392		
	HVP3023	Self-compressive cannulated screw		23	03701091001408		
	HVP3025	Self-compressive cannulated screw		25	03701091001415		
	HVP3027	Self-compressive cannulated screw		27	03701091001422		
	HVP3029	Self-compressive cannulated screw		29	03701091001439		
	HVP3031	Self-compressive cannulated screw		31	03701091001446		

EXRAY 35							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HVP3511	Self-compressive cannulated screw	3,5	11	03701091001477	IIb	Appendix : VIII Rule : 8
	HVP3513	Self-compressive cannulated screw		13	03701091001484		
	HVP3515	Self-compressive cannulated screw		15	03701091001491		
	HVP3517	Self-compressive cannulated screw		17	03701091001507		
	HVP3519	Self-compressive cannulated screw		19	03701091001514		
	HVP3521	Self-compressive cannulated screw		21	03701091001521		
	HVP3523	Self-compressive cannulated screw		23	03701091001538		
	HVP3525	Self-compressive cannulated screw		25	03701091001545		
	HVP3527	Self-compressive cannulated screw		27	03701091001552		
	HVP3529	Self-compressive cannulated screw		29	03701091001569		
	HVP3531	Self-compressive cannulated screw		31	03701091001576		



This declaration is based on:

- the technical file DT003, demonstrating compliance with essential requirements
- the full quality assurance system certification (certificate N° SX 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY.
- EC certificate (certificate N°HD 60145960 0001) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY, as per conformity assessment procedure of Annex II, excluding section 4 of the Directive 93/42/EEC

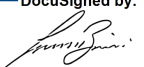
The EXRAY® and TIGERTRACK® screw system are indicated as an attachment system for small bone fractures or minor bone reconstruction in mature skeleton in the following cases:

- monocortical or bicortical osteotomies of the foot
- metatarsal or distal or proximal metacarpal osteotomies
- fusion of the first metatarsophalangeal and interphalangeal joint
- attachment in the case of treatment of Hallux Valgus (e.g. scarf osteotomy, chevron osteotomy, etc.)
- Akin osteotomy
- Weil osteotomy (Weil's snap-off screw only)

This for the period of validity of the certificate, ie until: 2024/05/26.

*NB: this declaration is only valid in combination with a specific batch release document.*

Luigi BIVI  
President

DocuSigned by:  
  
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