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Chassieu, on 2020/07/16

EC CONFORMITY DECLARATION



TIGER22, TIGER29, TIGER45, EXRAY30 & EXRAY35

ADSM, represented by Lui BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices:


TIGER 22							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV2211	Self-compressive cannulated screw	2,2	11	3701091000982	IIb	Appendix : VIII Rule : 8
	HV2213	Self-compressive cannulated screw		13	3701091000999		
	HV2215	Self-compressive cannulated screw		15	3701091001002		
	HV2217	Self-compressive cannulated screw		17	3701091001019		
	HV2219	Self-compressive cannulated screw		19	3701091001026		
	HV2221	Self-compressive cannulated screw		21	3701091001033		
	HV2223	Self-compressive cannulated screw		23	3701091001040		
	HV2225	Self-compressive cannulated screw		25	3701091001057		
	HV2227	Self-compressive cannulated screw		27	3701091001064		
	HV2229	Self-compressive cannulated screw		29	3701091001071		
	HV2231	Self-compressive cannulated screw		31	3701091001088		
	HV2233	Self-compressive cannulated screw		33	3701091001095		
	HV2235	Self-compressive cannulated screw		35	3701091001101		
	HV2237	Self-compressive cannulated screw		37	3701091001118		
	HV2239	Self-compressive cannulated screw		39	3701091001125		
	HV2241	Self-compressive cannulated screw		41	3701091001132		
HV2243	Self-compressive cannulated screw	43	3701091001149				
HV2245	Self-compressive cannulated screw	45	3701091001156				


TIGER 29							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HV2911	Self-compressive cannulated screw	2,9	11	3701091001163	IIb	Appendix : VIII Rule : 8
	HV2913	Self-compressive cannulated screw		13	3701091001170		
	HV2915	Self-compressive cannulated screw		15	3701091001187		
	HV2917	Self-compressive cannulated screw		17	3701091001194		
	HV2919	Self-compressive cannulated screw		19	3701091001200		
	HV2921	Self-compressive cannulated screw		21	3701091001217		
	HV2923	Self-compressive cannulated screw		23	3701091001224		
	HV2925	Self-compressive cannulated screw		25	3701091001231		
	HV2927	Self-compressive cannulated screw		27	3701091001248		
	HV2929	Self-compressive cannulated screw		29	3701091001255		
	HV2931	Self-compressive cannulated screw		31	3701091001262		
	HV2933	Self-compressive cannulated screw		33	3701091001279		

	HV2935	Self-compressive cannulated screw		35	3701091001286		
	HV2937	Self-compressive cannulated screw		37	3701091001293		
	HV2939	Self-compressive cannulated screw		39	3701091001309		
	HV2941	Self-compressive cannulated screw		41	3701091001316		
	HV2943	Self-compressive cannulated screw		43	3701091001323		
	HV2945	Self-compressive cannulated screw		45	3701091001330		

TIGER 45							
Illustration	Reference	Designation	Ø	Length	GTIN code	Class	Classification rule
	HV4525	Self-compressive cannulated screw	4,5	25	3701091001774	IIB	Appendix : VIII Rule : 8
	HV4527	Self-compressive cannulated screw		27	3701091001781		
	HV4529	Self-compressive cannulated screw		29	3701091001798		
	HV4531	Self-compressive cannulated screw		31	3701091001804		
	HV4533	Self-compressive cannulated screw		33	3701091001811		
	HV4535	Self-compressive cannulated screw		35	3701091001828		
	HV4537	Self-compressive cannulated screw		37	3701091001835		
	HV4539	Self-compressive cannulated screw		39	3701091001842		
	HV4541	Self-compressive cannulated screw		41	3701091001859		
	HV4543	Self-compressive cannulated screw		43	3701091001866		
	HV4545	Self-compressive cannulated screw		45	3701091001873		
	HV4547	Self-compressive cannulated screw		47	3701091001880		
	HV4549	Self-compressive cannulated screw		49	3701091001897		
	HV4551	Self-compressive cannulated screw		51	3701091001903		
	HV4553	Self-compressive cannulated screw		53	3701091001910		
	HV4555	Self-compressive cannulated screw		55	3701091001927		
	HV4557	Self-compressive cannulated screw		57	3701091001934		
HV4559	Self-compressive cannulated screw	59	3701091001941				
HV4561	Self-compressive cannulated screw	61	3701091001958				
	CT4525	Self-compressive, continuous thread, cannulated screw	4,0	25	3701091001965	IIB	Appendix : VIII Rule : 8
	CT4527	Self-compressive, continuous thread, cannulated screw		27	3701091001972		
	CT4529	Self-compressive, continuous thread, cannulated screw		29	3701091001989		
	CT4531	Self-compressive, continuous thread, cannulated screw		31	3701091001996		
	CT4533	Self-compressive, continuous thread, cannulated screw		33	3701091002009		
	CT4535	Self-compressive, continuous thread, cannulated screw		35	3701091002016		
	CT4537	Self-compressive, continuous thread, cannulated screw		37	3701091002023		
	CT4539	Self-compressive, continuous thread, cannulated screw		39	3701091002030		
	CT4541	Self-compressive, continuous thread, cannulated screw		41	3701091002047		
	CT4543	Self-compressive, continuous thread, cannulated screw		43	3701091002054		
	CT4545	Self-compressive, continuous thread, cannulated screw		45	3701091002061		
	CT4547	Self-compressive, continuous thread, cannulated screw		47	3701091002078		
	CT4549	Self-compressive, continuous thread, cannulated screw		49	3701091002085		
	CT4551	Self-compressive, continuous thread, cannulated screw		51	3701091002092		
CT4553	Self-compressive, continuous thread, cannulated screw	53	3701091002108				

	CT4555	Self-compressive, continuous thread, cannulated screw		55	3701091002115		
	CT4557	Self-compressive, continuous thread, cannulated screw		57	3701091002122		
	CT4559	Self-compressive, continuous thread, cannulated screw		59	3701091002139		
	CT4561	Self-compressive, continuous thread, cannulated screw		61	3701091002146		

EXRAY 30							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HVP3011	Self-compressive cannulated screw	3,0	11	3701091001347	IIb	Appendix : VIII Rule : 8
	HVP3013	Self-compressive cannulated screw		13	3701091001354		
	HVP3015	Self-compressive cannulated screw		15	3701091001361		
	HVP3017	Self-compressive cannulated screw		17	3701091001378		
	HVP3019	Self-compressive cannulated screw		19	3701091001385		
	HVP3021	Self-compressive cannulated screw		21	3701091001392		
	HVP3023	Self-compressive cannulated screw		23	3701091001408		
	HVP3025	Self-compressive cannulated screw		25	3701091001415		
	HVP3027	Self-compressive cannulated screw		27	3701091001422		
	HVP3029	Self-compressive cannulated screw		29	3701091001439		
	HVP3031	Self-compressive cannulated screw		31	3701091001446		

EXRAY 35							
Illustration	Reference	Designation	∅	Length	GTIN code	Class	Classification rule
	HVP3511	Self-compressive cannulated screw	3,5	11	3701091001477	IIb	Appendix : VIII Rule : 8
	HVP3513	Self-compressive cannulated screw		13	3701091001484		
	HVP3515	Self-compressive cannulated screw		15	3701091001491		
	HVP3517	Self-compressive cannulated screw		17	3701091001507		
	HVP3519	Self-compressive cannulated screw		19	3701091001514		
	HVP3521	Self-compressive cannulated screw		21	3701091001521		
	HVP3523	Self-compressive cannulated screw		23	3701091001538		
	HVP3525	Self-compressive cannulated screw		25	3701091001545		
	HVP3527	Self-compressive cannulated screw		27	3701091001552		
	HVP3529	Self-compressive cannulated screw		29	3701091001569		
	HVP3531	Self-compressive cannulated screw		31	3701091001576		

Comply with all the provisions of Directive 93/42/CEE dated June, 14th 1993, modified by the Directive 2007/47/CEE dated September, 5th 2007 and with provisions from the Public Health Code, section 5, book number II, 1st Title (article R665-1 et al., if applicable).

This declaration is based on:

- the technical file DT003, demonstrating compliance with essential requirements
- the full quality assurance system certification (certificate N° SX 60145958 0001) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY.

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

