


ADSM


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Chassieu, on 2021/04/29


EC CONFORMITY DECLARATION
TIGER18, TIGER25, TIGER WEIL, EXRAY20

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

EXRAY 20									
Illustration	Reference	Designation	∅	Total Length	Working Length	UDI-DI code	BUDI-DI code	Class	Classification rule
	PW2060	Snap-off threaded pin	2	60	31	3701091001750	37010910D	IIb	Appendix : IX Rule : 8
	PW20100	Snap-off threaded pin		100	69	3701091001767	T002003TIG EXRWB		

TIGER 18								
Illustration	Reference	Designation	∅	Length	UDI-DI code	BUDI-DI code	Class	Classification rule
	HV1813	Snap-off threaded pin	1,8	13	3701091000517	37010910D T002003TIGEXRWB	IIb	Appendix : IX Rule : 8
	HV1815	Snap-off threaded pin		15	3701091000524			
	HV1817	Snap-off threaded pin		17	3701091000531			
	HV1819	Snap-off threaded pin		19	3701091000548			
	HV1821	Snap-off threaded pin		21	3701091000555			
	HV1823	Snap-off threaded pin		23	3701091000562			
	HV1825	Snap-off threaded pin		25	3701091000579			
	HV1827	Snap-off threaded pin		27	3701091000586			
	HV1829	Snap-off threaded pin		29	3701091000593			
	HV1831	Snap-off threaded pin		31	3701091000609			
	HV1833	Snap-off threaded pin		33	3701091000616			
	HV1835	Snap-off threaded pin		35	3701091000623			
	HV1837	Snap-off threaded pin		37	3701091000630			
	HV1839	Snap-off threaded pin		39	3701091000647			
	HV1841	Snap-off threaded pin		41	3701091000654			
	HV1843	Snap-off threaded pin		43	3701091000661			
HV1845	Snap-off threaded pin	45	3701091000678					

TIGER 25								
Illustration	Reference	Designation	∅	Length	UDI-DI code	BUDI-DI code	Class	Classification rule
	HV2513	Snap-off threaded pin	2,5	13	3701091000685	370109100DT002003TIGEXRWB	Iib	Appendix : IX Rule : 8
	HV2515	Snap-off threaded pin		15	3701091000692			
	HV2517	Snap-off threaded pin		17	3701091000708			
	HV2519	Snap-off threaded pin		19	3701091000715			
	HV2521	Snap-off threaded pin		21	3701091000722			
	HV2523	Snap-off threaded pin		23	3701091000739			
	HV2525	Snap-off threaded pin		25	3701091000746			
	HV2527	Snap-off threaded pin		27	3701091000753			
	HV2529	Snap-off threaded pin		29	3701091000760			
	HV2531	Snap-off threaded pin		31	3701091000777			
	HV2533	Snap-off threaded pin		33	3701091000784			
	HV2535	Snap-off threaded pin		35	3701091000791			
	HV2537	Snap-off threaded pin		37	3701091000807			
	HV2539	Snap-off threaded pin		39	3701091000814			
	HV2541	Snap-off threaded pin		41	3701091000821			
	HV2543	Snap-off threaded pin		43	3701091000838			
HV2545	Snap-off threaded pin	45	3701091000845					

TIGER W								
Illustration	Reference	Designation	∅	Length	UDI-DI code	BUDI-DI code	Class	Classification rule
	WE0009	Snap-off Weil screw	2,2	9	3701091000852	370109100DT002003TIGEXRWB	Iib	Appendix : IX Rule : 8
	WE0010	Snap-off Weil screw		10	3701091000869			
	WE0011	Snap-off Weil screw		11	3701091000876			
	WE0012	Snap-off Weil screw		12	3701091000883			
	WE0013	Snap-off Weil screw		13	3701091000890			
	WE0014	Snap-off Weil screw		14	3701091000906			
	WE0015	Snap-off Weil screw		15	3701091000913			
	WE0016	Snap-off Weil screw		16	3701091000920			
	WE0017	Snap-off Weil screw		17	3701091000937			
	WE0018	Snap-off Weil screw		18	3701091000944			
	WE0019	Snap-off Weil screw		19	3701091000951			
	WE0020	Snap-off Weil screw		20	3701091000968			
	WE0021	Snap-off Weil screw		21	3701091000975			

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 DT002, demonstrating compliance with essential requirements
- the quality assurance system for medical devices
- EC certificate (certificate N°HD 60145960 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

