



ADSM

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Single registration number : FR-MF-000001222

Chassieu, October 22nd , 2024

EU DECLARATION OF CONFORMITY

ADSM, represented by Luigi BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices comply with all the provisions of Medical Device Regulation dated April, 5th 2017 and with provisions from the Public Health Code, section 5, book number II, 1st Title (article R665-1 et al., if applicable).

MISTERI									
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication		
KW12150TTRS-0301	STERILE KIRSCHNER WIRE WITH THREADED TIP	IIB	Annex VIII, Chapter III Rule 8	03701091002535	P091203	037010910DT007KWSTEPH	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. Kirschner wires (transient use) These devices are indicated for: - temporary stabilization of bone fragments during surgery - as a guidance system for product-specific medical devices Kirschner wires (long-term use) These devices are indicated for long-term fixation of bone segments in order to obtain bone fusion, both in a percutaneous or open surgical approach. Guide wires (transient use) These devices are indicated as a guidance system for product-specific medical devices		
KW16150TTRS-0301				03701091002559					
KW18150TTRS-0301				03701091002573					
KW20150TTRS-0301				03701091002597					
KW25150TTRS-0301				03701091002610					
KW25200TTRS-0301				03701091002634					
KW30150TTRS-0301				03701091002658					
KW16190TTRS-0301				03701091002672					
KW06070TRS-0301				03701091002696					
KW08070TRS-0301	03701091002719								
KW08100TRS-0301	03701091007219								
KW08100TRS-0102	03701091002733								
KW08150TRS-0301	03701091002757								
KW10070TRS-0301	03701091007226								
KW10070TRS-0102	03701091002771								
KW10100TRS-0301	03701091007233								
KW10100TRS-0102	03701091002795								
KW10150TRS-0301	03701091002818								
KW10280TRS-0301	03701091002832								
KW10310TRS-0301	03701091002856								
KW12150TRS-0301	03701091002870								
KW12150TRS-0102	03701091002887								
KW12280TRS-0301	03701091002900								
KW12310TRS-0301	03701091002924								
KW13100TRS-0301	03701091002948								
KW13100TRS-0102	03701091007318								
KW13050TRS-0301	03701091002962								
KW13050TRS-0102	03701091007240								
KW14150TRS-0301	03701091002986								
KW14280TRS-0301	03701091003006								
KW14310TRS-0301	03701091003020								
KW15100TRS-0301	03701091007325								
KW15100TRS-0102	03701091003044								
	STERILE KIRSCHNER WIRE WITH TROCAR TIP					037010910DT007KWSTEPH			



KW15150TRS-0301				03701091007332			
KW15150TRS-0102				03701091003068			
KW16150TRS-0301				03701091003082			
KW16280TRS-0301				03701091003105			
KW16310TRS-0301				03701091003129			
KW18150TRS-0301				03701091003143			
KW18280TRS-0301				03701091003167			
KW18310TRS-0301				03701091003181			
KW20150TRS-0301				03701091003204			
KW20280TRS-0301				03701091003228			
KW20310TRS-0301				03701091003242			
KW20400TRS-0301				03701091003266			
KW22450TRS-0301				03701091003280			
KW25150TRS-0301				03701091003303			
KW25280TRS-0301				03701091003327			
KW25310TRS-0301				03701091003341			
KW25400TRS-0301				03701091003365			
KW30150TRS-0301				03701091003389			
KW30280TRS-0301				03701091003402			
KW30310TRS-0301				03701091003426			
KW30400TRS-0301				03701091003440			
GW32444TS-0101	STERILE PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091003464	L091001	037010910DT007GWST EN5	
GW32450TS-0101				03701091003488			
GW32508TS-0101				03701091003501			

MISTERI											
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication				
KW12150TTR	KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091002542	P091203	037010910DT007KWNONST EUZ	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. Kirschner wires (transient use) These devices are indicated for: - temporary stabilization of bone fragments during surgery - as a guidance system for product-specific medical devices Kirschner wires (long-term use) These devices are indicated for long-term fixation of bone segments in order to obtain bone fusion, both in a percutaneous or open surgical approach. Guide wires (transient use) These devices are indicated as a guidance system for product-specific medical devices				
KW16150TTR				03701091002566							
KW18150TTR				03701091002580							
KW20150TTR				03701091002603							
KW25150TTR				03701091002627							
KW25200TTR				03701091002641							
KW30150TTR				03701091002665							
KW16190TTR				03701091002689							
KW06070TR	03701091002702										
KW08070TR	03701091002726										
KW08100TR	KIRSCHNER WIRE WITH TROCAR TIP							03701091002740		037010910DT007KWNONST STEPW	
KW08150TR								03701091002764		037010910DT007KWNONST Z	
KW10070TR								03701091002788			
KW10100TR								03701091002801			
KW10150TR								03701091002825			
KW10280TR								03701091002849			
KW10310TR				03701091002863							
KW12150TR				03701091002894							
KW12280TR				03701091002917							
KW12310TR				03701091002931							
KW13100TR			03701091002955								
KW13050TR			03701091002979								

KW14150TR				03701091002993		
KW14280TR				03701091003013		
KW14310TR				03701091003037		
KW15100TR				03701091003051		
KW15150TR				03701091003075		
KW16150TR				03701091003099		
KW16280TR				03701091003112		
KW16310TR				03701091003136		
KW18150TR				03701091003150		
KW18280TR				03701091003174		
KW18310TR				03701091003198		
KW20150TR				03701091003211		
KW20280TR				03701091003235		
KW20310TR				03701091003259		
KW20400TR				03701091003273		
KW22450TR				03701091003297		
KW25150TR				03701091003310		
KW25280TR				03701091003334		
KW25310TR				03701091003358		
KW25400TR				03701091003372		
KW30150TR				03701091003396		
KW30280TR				03701091003419		
KW30310TR				03701091003433		
KW30400TR				03701091003457		
GW32444T				03701091003471		
GW32450T	PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III Rule 6	03701091003495	L091001	037010910DT007GWNONSTESM
GW32508T				03701091003518		

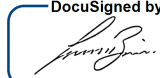
This declaration is based on:

- The technical file DT007 demonstrating compliance with general safety and performance requirements of MDR 2017/745
- 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.
- MDR 2017/745 EC certificate (certificate N°HZ 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY, as per conformity assessment procedure of Annex IX, Chapter I, Sections 2 and 3 and Chapter III.

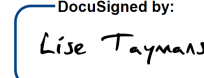
This for the period of validity of the certificate until: 2026/10/12.

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

Luigi BIVI
President

DocuSigned by:

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Lise ROLLY TAYMANS
PRRC

DocuSigned by:

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