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Single registration number : FR-MF-000001222

Chassieu, September 13th 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).

STERILEBITZ							
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication
110.25.000-SB	STERILE KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091007257	P091203	037010910DT007KWS TEPH	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
299.20.150-SB				03701091007127			
02.01362.116-SB				03701091007103			
290.06.070-SB	03701091007080			037010910DT007KWSTEPH			
290.08.070-SB	03701091007066						
290.10.150-SB	03701091007042						
290.12.150-SB	03701091007028						
290.14.150-SB	03701091007004						
290.14.280-SB	03701091006984						
290.16.150-SB	03701091006960						
290.16.280-SB	03701091006946						
290.18.150-SB	03701091006922						
290.18.280-SB	03701091006908						
290.20.150-SB	03701091006885						
290.20.280-SB	03701091006861						
290.25.150-SB	03701091006847	L091001	Annex VIII, Chapter III Rule 6	03701091006786	037010910DT007G WSTEN5		
290.25.280-SB	03701091006823						
290.25.310-SB	03701091006809						
2810-01-175-SB	STERILE PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091006786	L091001	037010910DT007G WSTEN5	
00-2490-450-32-SB				03701091006762			

STERILEBITZ												
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication					
110.25.000-R	KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091007264	P091203	037010910DT007KWN ONSTEUZ	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					
299.20.150-R				03701091007110								
02.01362.116-R				03701091007097								
290.06.070-R	KIRSCHNER WIRE WITH TROCAR TIP			03701091007073		037010910DT007KWN ONSTEUZ						
290.08.070-R				03701091007059								
290.10.150-R				03701091007035								
290.12.150-R				03701091007011								
290.14.150-R				03701091006991								
290.14.280-R				03701091006977								
290.16.150-R				03701091006953								
290.16.280-R				03701091006939								
290.18.150-R				03701091006915								
290.18.280-R				03701091006892								
290.20.150-R				03701091006878								
290.20.280-R				03701091006854								
290.25.150-R				03701091006830								
290.25.280-R				03701091006816								
290.25.310-R				03701091006793								
2810-01-175-R				PARTIAL THREADED GUIDE WIRE				IIa	Annex VIII, Chapter III Rule 6	03701091006779	L091001	037010910 DT007GWN ONSTESM
00-2490-450-32-R										03701091006755		

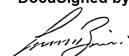
This declaration is based on:

- 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

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Lise ROLLY TAYMANS
PRRC

DocuSigned by:

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