



ADSM

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Single registration number : FR-MF-000001222

Chassieu, March 21, 2025

EC CONFORMITY DECLARATION

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
DB43145TFS-0101	STERILE TWO-FLUTED DRILL BIT WITH QUICK COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091003525	L1104	037010910DT009DBSTEHB	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
DB43195TFS-0101							
DB43300TFS-0101							
DB33195TFS-0101							
DB33230TFS-0101							
DB25245TFS-0101							
DB33245TFS-0101							
DB43245TFS-0101							
DB40245TFS-0101							
DB25180TFS-0101							
DB30195TFS-0101							
DB35195TFS-0101							
DB45195TFS-0101							
DB25265TFS-0101							
DB33265TFS-0101							
DB43265TFS-0101							
DB33195FF2S-0101	STERILE FOUR-FLUTED CANNULATED DRILL BIT WITH QUICK COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091003846	L1104	037010910DT009BURSTIE7Q	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
DB33195FF1S-0101	STERILE SHANNON BURR SIZE S			03701091003990			
SB2008S-0105	STERILE SHANNON BURR SIZE S	IIa	Annex VIII, Chapter III Rule 6	03701091003860	L1104	037010910DT009BURSTIE7Q	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
SB2012S-0105	STERILE SHANNON BURR SIZE L			03701091003884			
SBS2012S-0105	STERILE SHANNON BURR ISHAM			03701091003907			
SB2022S-0105	STERILE SHANNON BURR SIZE XL			03701091003921			
WB2913S-0105	STERILE WEDGE BURR			03701091003945			
WB4313S-0105				03701091003969			



MISTERI								
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication	
DB43145TF	TWO-FLUTED DRILL BIT WITH QUICK COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091003532	L1104	037010910DT009DBNONSTEF5	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.	
DB43195TF				03701091003556				
DB43300TF				03701091003570				
DB33195TF				03701091003594				
DB33230TF				03701091003617				
DB25245TF				03701091003631				
DB33245TF				03701091003655				
DB43245TF				03701091003679				
DB40245TF				03701091003693				
DB25180TF				03701091003716				
DB30195TF				03701091003730				
DB35195TF				03701091003754				
DB45195TF				03701091003778				
DB25265TF				03701091003792				
DB33265TF				03701091003815				
DB43265TF	03701091003839	IIa	Annex VIII, Chapter III Rule 6	03701091003853	L1104	037010910DT009DBNONSTEF5	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.	
DB33195FF2	FOUR-FLUTED CANNULATED DRILL BIT WITH QUICK COUPLING			03701091004003				
DB33195FF1				03701091004003				
SB2008	SHANNON BURR SIZE S			03701091003877				037010910DT009BURNONSTEQJ
SB2012	SHANNON BURR SIZE L			03701091003891				
SBS2012	SHANNON BURR ISHAM			03701091003914				
SB2022	SHANNON BURR SIZE XL			03701091003938				
WB2913	WEDGE BURR			03701091003952				
WB4313				03701091003976				

Kit EXRAY							
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication
HV9008	CANNULATED MILLING TOOL FOR TIGER22	IIa	Annex VIII, Chapter III Rule 6	03701091005116	L1104	037010910DT009BURNONSTEQJ	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
HV9009	CANNULATED MILLING TOOL FOR TIGER29			03701091005123			
HV9040-013	CANNULATED STEP DRILL			03701091004065		037010910DT009DBNONSTEF5	
HV9040-015				03701091004072			
HV9040-017				03701091004089			
HV9040-019				03701091004096			
HV9040-021				03701091004102			
HV9040-023				03701091004119			
HV9040-025				03701091004126			
HV9040-027				03701091004133			
HV9040-029				03701091004140			
HV9040-031				03701091004157			
HV9041-013	STEP DRILL			03701091004188			
HV9041-015				03701091004195			
HV9041-017				03701091004201			
HV9041-019		03701091004218					
HV9041-021		03701091004225					
HV9041-023		03701091004232					
HV9041-025		03701091004249					
HV9041-027		03701091004256					
HV9041-029		03701091004263					
HV9041-031		03701091004270					



Kit TIGERTRACK							
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication
HV9024	SHORT STEP DRILL	IIa	Annex VIII, Chapter III Rule 6	03701091003983	L1104	037010910 DT009DBN ONSTEF5	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
HV9026	LONG STEP DRILL			03701091004027			
HV9025	CANNULATED SHORT STEP DRILL			03701091004010			
HV9027	CANNULATED LONG STEP DRILL			03701091004034			
HV9006A	LONG STEP DRILL			03701091005109			
HV9032	CANNULATED SHORT STEP DRILL			03701091004041			
HV9033	CANNULATED LONG STEP DRILL			03701091004058			
B01-012010	Cannulated Drill Ø2			03701091007547		37010910D T009DBNO NSTEF5	
B01-013010	Cannulated Countersink Ø3			03701091007554		37010910D T009DBNO NSTEF5	



Kit TOEGRIP CLASSIC / Kit TOEGRIP EVO							
Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication
TG0240-Starter	P1 COMPACTOR - STARTER - AO COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091004423	L1104	037010910DT009COMPACTN8	<p>These medical devices are only indicated for patient with a body mass superior or equal to 10kg.</p> <p>These devices are indicated for bone preparation during orthopaedic surgery.</p>
TG0240-XS	P1 COMPACTOR - XS - AO COUPLING			03701091004430			
TG0240-SS	P1 COMPACTOR - S - AO COUPLING			03701091004447			
TG0240-MM	P1 COMPACTOR - M - AO COUPLING			03701091004454			
TG0240-LL	P1 COMPACTOR - L - AO COUPLING			03701091004461			
TG0241-Starter	P2 COMPACTOR - STARTER - AO COUPLING			03701091004478			
TG0241-XS	P2 COMPACTOR - XS - AO COUPLING			03701091004485			
TG0241-SS	P2 COMPACTOR - S - AO COUPLING			03701091004492			
TG0241-MM	P2 COMPACTOR - M - AO COUPLING			03701091004508			
TG0241-LL	P2 COMPACTOR - L - AO COUPLING			03701091004515			
TG0113	TOEGRIP CLASSIC - STARTER P1 COMPACTOR - WIRE COUPLING			03701091004737			
TG0114	TOEGRIP CLASSIC - EXTRA SMALL P1 COMPACTOR - WIRE COUPLING			03701091004744			
TG0115	TOEGRIP CLASSIC - SMALL P1 COMPACTOR - WIRE COUPLING			03701091004751			
TG0116	TOEGRIP CLASSIC - MEDIUM P1 COMPACTOR - WIRE COUPLING			03701091004768			
TG0117	TOEGRIP CLASSIC - LARGE P1 COMPACTOR - WIRE COUPLING			03701091004775			
TG0119	TOEGRIP CLASSIC - EXTRA SMALL P2 COMPACTOR - WIRE COUPLING			03701091004782			
TG0120	TOEGRIP CLASSIC - SMALL P2 COMPACTOR - WIRE COUPLING	03701091004799					
TG0121	TOEGRIP CLASSIC - MEDIUM P2 COMPACTOR - WIRE COUPLING	03701091004805					
TG0122	TOEGRIP CLASSIC - LARGE P2 COMPACTOR - WIRE COUPLING	03701091004812					
TG0123	TOEGRIP CLASSIC - EXTRA LARGE P2 COMPACTOR - WIRE COUPLING	03701091004829					
TG0124	TOEGRIP CLASSIC - STARTER P2 COMPACTOR - WIRE COUPLING	03701091004836					



TG0242-Starter	P1 CANNULATED COMPACTOR - STARTER - AO COUPLING			03701091004522		
TG0242-XS	P1 CANNULATED COMPACTOR - XS - AO COUPLING			03701091004539		
TG0242-SS	P1 CANNULATED COMPACTOR - S - AO COUPLING			03701091004546		
TG0242-MM	P1 CANNULATED COMPACTOR - M - AO COUPLING			03701091004553		
TG0242-LL	P1 CANNULATED COMPACTOR - L - AO COUPLING			03701091004560		
TG0243-STARTER	P2 CANNULATED COMPACTOR - STARTER - AO COUPLING			03701091004867		
TG0243-XS	P2 CANNULATED COMPACTOR - XS - AO COUPLING			03701091004874		
TG0243-SS	P2 CANNULATED COMPACTOR - S - AO COUPLING			03701091004881		
TG0243-MM	P2 CANNULATED COMPACTOR - M - AO COUPLING			03701091004898		
TG0243-LL	P2 CANNULATED COMPACTOR - L - AO COUPLING			03701091004904		
TG0005	TOEGRIP CLASSIC REAMER			03701091004669	037010910DT009REAMER 3G	
TG0010	CALCAR REAMER			03701091004713		
TGE0010	CANNULATED CALCAR REAMER			03701091005079		

This declaration is based on:

- The technical file DT009 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.

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

Lise ROLLY TAYMANS
PRRC

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