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REF : DT003-016-EN Rev12

Single registration number : FR-MF-000001222

Chassieu, July 3, 2025

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).

This declaration is based on:
-the technical file DT003 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, ie until: 2026-10-12.

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

DocuSigned by:

Luigi BIVI
President

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DocuSigned by:

Lise ROLLY TAYMANS
PRRC

Lise Taymans

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Indications

The screw system is indicated as an attachment system for small bone fractures or minor bone reconstruction in mature skeleton in the following cases:
- monocortical or bicortical osteotomies of the foot
- metatarsal or distal or proximal metacarpal osteotomies
- fusion of the first metatarsophalangeal and interphalangeal joint
- attachment in the case of treatment of Hallux Valgus (e.g. scarf osteotomy, chevron osteotomy, etc.)
- Akin osteotomy

Reference	Designation	Class	Classification rule	UDI-DI code	EMDN code (CND)	BUDI-DI code	Brand Name
A01-003010	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007585	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003012	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007592	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003014	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007912	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003016	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007905	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003018	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007899	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003020	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007882	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003022	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007875	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003024	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007868	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003026	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007851	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003028	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007844	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003030	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007837	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003032	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007820	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003034	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007813	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003036	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007806	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003038	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007790	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003040	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007783	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003042	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007776	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-003044	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007769	P09120603	037010910DT003TIGERMETHE	TIGER 30
A01-013014	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007633	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013016	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007615	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013018	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007622	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013020	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007639	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013022	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007646	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013024	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007653	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013026	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007752	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013028	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007745	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013030	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007738	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013032	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007721	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013034	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007714	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013036	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007707	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013038	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007691	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013040	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007684	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013042	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007677	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
A01-013044	EN-30° Flanged Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091007660	P09120603	037010910DT003TIGERMETHE	TIGER 30 FLANGE
CT4525	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001965	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4527	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001972	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4529	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001989	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4531	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001996	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4533	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002009	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4535	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002016	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4537	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002023	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4539	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002030	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4541	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002047	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4543	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002054	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4545	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002061	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4547	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002078	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4549	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002085	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4551	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002092	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4553	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002108	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4555	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002115	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4557	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002122	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4559	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002139	P09120603	037010910DT003TIGERMETHE	TIGER 45
CT4561	EN-Self-compressive, continuous thread, cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091002146	P09120603	037010910DT003TIGERMETHE	TIGER 45
HV2211	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091000982	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2213	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091000999	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2215	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001002	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2217	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001019	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2219	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001026	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2221	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001033	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2223	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001040	P09120603	037010910DT003TIGERMETHE	TIGER 22
HV2225	EN-Self-compressive cannulated screw	IIb	Annex VIII, Chapter III rule 8	03701091001057	P09120603	037010910DT003TIGERMETHE	TIGER 22

2/2