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REF : DT002-016-EN Rev11

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 DT002 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


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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
HV1813	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000517	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1815	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000524	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1817	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000531	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1819	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000548	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1821	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000555	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1823	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000562	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1825	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000579	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1827	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000586	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1829	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000593	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1831	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000609	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1833	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000616	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1835	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000623	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1837	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000630	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1839	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000647	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1841	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000654	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1843	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000661	P09120601	037010910DT002TIGER18HB	TIGER 18
HV1845	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000678	P09120601	037010910DT002TIGER18HB	TIGER 18
HV2513	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000685	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2515	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000692	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2517	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000708	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2519	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000715	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2521	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000722	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2523	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000739	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2525	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000746	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2527	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000753	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2529	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000760	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2531	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000777	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2533	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000784	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2535	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000791	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2537	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000807	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2539	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000814	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2541	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000821	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2543	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000838	P09120601	037010910DT002TIGER25H8	TIGER 25
HV2545	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091000845	P09120601	037010910DT002TIGER25H8	TIGER 25
PW20100	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091001767	P09120604	037010910DT002EXRAY20K2	EXRAY® 20
PW2060	EN-Snap-off threaded pin	IIB	Annex VIII, Chapter III rule 8	03701091001750	P09120604	037010910DT002EXRAY20K2	EXRAY® 20
WE0009	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000852	P09120601	037010910DT002TIGERWYD	TIGER W
WE0010	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000869	P09120601	037010910DT002TIGERWYD	TIGER W
WE0011	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000876	P09120601	037010910DT002TIGERWYD	TIGER W
WE0012	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000883	P09120601	037010910DT002TIGERWYD	TIGER W
WE0013	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000890	P09120601	037010910DT002TIGERWYD	TIGER W
WE0014	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000906	P09120601	037010910DT002TIGERWYD	TIGER W
WE0015	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000913	P09120601	037010910DT002TIGERWYD	TIGER W
WE0016	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000920	P09120601	037010910DT002TIGERWYD	TIGER W
WE0017	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000937	P09120601	037010910DT002TIGERWYD	TIGER W
WE0018	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000944	P09120601	037010910DT002TIGERWYD	TIGER W
WE0019	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000951	P09120601	037010910DT002TIGERWYD	TIGER W
WE0020	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000968	P09120601	037010910DT002TIGERWYD	TIGER W
WE0021	EN-Snap-off Weil screw	IIB	Annex VIII, Chapter III rule 8	03701091000975	P09120601	037010910DT002TIGERWYD	TIGER W