



REF : DT001-016-EN Rev09

ADSM

7b rue Lavoisier
 69680 CHASSIEU - FRANCE
 Tel : +33 (0)4 28 71 03 10
 Fax : +33 (0)4 28 71 03 20
office@synchromedical.com

Single registration number : FR-MF-000001222

Chassieu, September 19, 2024

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).

Reference	Designation	Class	Classification rule	UDI-DI code	CND code	BUDI-DI code	Indication
TGXS00	ToeGrip Classic Extra-Small 0°	IIb	Annex VIII Chapter III Rule 8	03701091000166	P090603	037010910DT001TOEGRIPQR	TOEGRIP®CLASSIC and TOEGRIP®EVO implants are indicated for the reconstruction of minor bones limited to the interdigital fusion of the toes on the mature skeleton in the following cases: <ul style="list-style-type: none"> • Rigid/fixed deformations: <ul style="list-style-type: none"> - Affecting the proximal interphalangeal joint (PIJ). - Hammer toe deformities. - Claw toe deformities (PIP and DIP joints). • Hammer toe revision surgeries • Shortening osteotomies of the proximal phalanx
TGXS10	ToeGrip Classic Extra-Small 10°			03701091000173			
TGXS20	ToeGrip Classic Extra-Small 20°			03701091000180			
TGSS00	ToeGrip Classic Small 0°			03701091000197			
TGSS10	ToeGrip Classic Small 10°			03701091000203			
TGSS20	ToeGrip Classic Small 20°			03701091000210			
TGMM00	ToeGrip Classic Medium 0°			03701091000227			
TGMM10	ToeGrip Classic Medium 10°			03701091000234			
TGMM20	ToeGrip Classic Medium 20°			03701091000241			
TGLL00	ToeGrip Classic Large 0°			03701091000258			
TGLL10	ToeGrip Classic Large 10°			03701091000265			
TGLL20	ToeGrip Classic Large 20°			03701091000272			
TGXL00	ToeGrip Classic Extra-Large 0°			03701091000289			
TGXL10	ToeGrip Classic Extra-Large 10°			03701091000296			
TGXL20	ToeGrip Classic Extra-Large 20°			03701091000302			
TGEXS00	ToeGrip Evo Extra-Small 0°			03701091001705			
TGEXS10	ToeGrip Evo Extra-Small 10°	03701091001712					
TGEXS20	ToeGrip Evo Extra-Small 20°	03701091001729					



TGESS00	ToeGrip Evo Small 0°			03701091001675			
TGESS10	ToeGrip Evo Small 10°			03701091001682			
TGESS20	ToeGrip Evo Small 20°			03701091001699			
TGEMM00	ToeGrip Evo Medium 0°			03701091001644			
TGEMM10	ToeGrip Evo Medium 10°			03701091001651			
TGEMM20	ToeGrip Evo Medium 20°			03701091001668			
TGELL00	ToeGrip Evo Large 0°			03701091001613			
TGELL10	ToeGrip Evo Large 10°			03701091001620			
TEGLL20	ToeGrip Evo Large 20°			03701091001637			
TGEXL00	ToeGrip Evo Extra- Large 0°			03701091001583			
TGEXL10	ToeGrip Evo Extra- Large 10°			03701091001590			
TGEXL20	ToeGrip Evo Extra- Large 20°			03701091001606			


This declaration is based on:

- the technical file DT001 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.

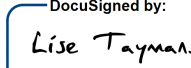
This for the period of validity of the certificate, ie until: 12/10/2026.

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

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