

ADSM

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Chassieu, on 2020/07/16

EC CONFORMITY DECLARATION

TOEGRIP CLASSIC & TOEGRIP EVO

ADSM, represented by Luigi BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices:

Illustration	Reference	Designation	Size	Angle	GTIN code	Class	Classification rule
	TGXS00	ToeGrip Classic Extra-Small 0°	X-Small	0°	3701091000166	IIb	Appendix : VIII Rule : 8
	TGXS10	ToeGrip Classic Extra-Small 10°	X-Small	10°	3701091000173		
	TGXS20	ToeGrip Classic Extra-Small 20°	X-Small	20°	3701091000180		
	TGSS00	ToeGrip Classic Small 0°	Small	0°	3701091000197		
	TGSS10	ToeGrip Classic Small 10°	Small	10°	3701091000203		
	TGSS20	ToeGrip Classic Small 20°	Small	20°	3701091000210		
	TGMM00	ToeGrip Classic Medium 0°	Medium	0°	3701091000227		
	TGMM10	ToeGrip Classic Medium 10°	Medium	10°	3701091000234		
	TGMM20	ToeGrip Classic Medium 20°	Medium	20°	3701091000241		
	TGLL00	ToeGrip Classic Large 0°	Large	0°	3701091000258		
	TGLL10	ToeGrip Classic Large 10°	Large	10°	3701091000265		
	TGLL20	ToeGrip Classic Large 20°	Large	20°	3701091000272		
	TGXL00	ToeGrip Classic Extra-Large 0°	X-Large	0°	3701091000289		
	TGXL10	ToeGrip Classic Extra-Large 10°	X-Large	10°	3701091000296		
	TGXL20	ToeGrip Classic Extra-Large 20°	X-Large	20°	3701091000302		
	TGEXS00	ToeGrip Evo Extra-Small 0°	X-Small	0°	3701091000166		
	TGEXS10	ToeGrip Evo Extra-Small 10°	X-Small	10°	3701091000173		
	TGEXS20	ToeGrip Evo Extra-Small 20°	X-Small	20°	3701091000180		
	TGESS00	ToeGrip Evo Small 0°	Small	0°	3701091000197		
	TGESS10	ToeGrip Evo Small 10°	Small	10°	3701091000203		
	TGESS20	ToeGrip Evo Small 20°	Small	20°	3701091000210		
	TGEMM00	ToeGrip Evo Medium 0°	Medium	0°	3701091000227		
	TGEMM10	ToeGrip Evo Medium 10°	Medium	10°	3701091000234		
	TGEMM20	ToeGrip Evo Medium 20°	Medium	20°	3701091000241		
	TGELL00	ToeGrip Evo Large 0°	Large	0°	3701091000258		
	TGELL10	ToeGrip Evo Large 10°	Large	10°	3701091000265		
	TGELL20	ToeGrip Evo Large 20°	Large	20°	3701091000272		
	TGEXL00	ToeGrip Evo Extra-Large 0°	X-Large	0°	3701091000289		
	TGEXL10	ToeGrip Evo Extra-Large 10°	X-Large	10°	3701091000296		
	TGEXL20	ToeGrip Evo Extra-Large 20°	X-Large	20°	3701091000302		

Comply with all the provisions of Directive 93/42/CEE dated June, 14th 1993, modified by the Directive 2007/47/CEE dated September, 5th 2007 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 DT001, demonstrating compliance with essential requirements
- the full quality assurance system certification (certificate N° SX 60145958 0001) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY.

This for the period of validity of the certificate, ie until: 2024/05/26.

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

Luigi BIVI
President

