



Declaration of conformity

Manufacturer:

*Fillauer Europe AB
SE-MF-000002626
Kung Hans Väg 2
S-192 68 Sollentuna
Sverige (Sweden)*

We declare under our sole responsibility that the products in **Appendix 1** are in conformity with the below-mentioned EU regulations and directives and specific standards.

Medical Device Regulation (MDR) 2017/745

Fillauer Europe AB

Kevin Moore
President

2021-06-15
Sollentuna, Sweden



Appendix I – Medical Devices

UDI	Product	Risk Class	Intended Use	Common Specifications
73333001021-DWG2	Dynamic Walk	I	Orthotic - Drop Foot Orthosis	
73333001021-DWP9U	Dynamic Walk padding	I	Orthotic - Drop foot Orthosis padding	
73333003014-FSHC	Foot Shell	I	Prosthetic – Foot Cover	
73333003061-DSJ8	Dreamskin	I	Prosthetic - Protective skin for lower limb	
73333003071-PFSDJ	Preflexed Sleeve	I	Prosthetic - Suction sleeve for socket suspension	
73333002061-NDFG9D	Natural Definition glove	I	Prosthetic - Protective skin for upper limb	
73333003081-ALPBY	ALP	I	Prosthetic - Lower limb, multi-plane alignment system	Tested according to ISO 10328
73333003074-PLKW	Prosthetic liner	I	Prosthetic - Lower limb liner	
73333003071-PSKP	Prosthetic sleeve	I	Prosthetic - Lower limb sleeve	
73333002012-PHGM	Passive hand	I	Prosthetic - Passive hand for natural form and use in opposition	
73333003051-VA-FEBK	Valves	I	Prosthetic - Valves for socket suspension	
73333005041-SSKZ	Silicone Stav	I	Transient vaginal expander not to be used more than 60min per day	
73333005021-TFCCB	Pre-cuts	I	Orthotic - Pre-cut carbon material for insoles and AFO's	
73333002061-HMSBX	Hand shells	I	Prosthetic - Natural form shell for mechanical and myoelectric device mechanics	
73333002032-ENGN	Endo arm	I	Prosthetic- Upper limb, endoskeletal, internal prosthetic structure	Tested according to ISO 22523 Annex A
73333003081-TA-FECN	Torsion adapter	I	Prosthetic - Lower limb torsional force absorber	Tested according to ISO 10328
73333002021-W-FE5N	Wrists	I	Prosthetic - Wrists	