



ABILIA

EU Declaration of Conformity

Doc. ID: 23883-2

Manufacturer	Abilia AB Råsundavägen 6 SE-169 67 Solna SWEDEN Phone: +46 8 594 694 00 Single Registration Number	SE-MF-000005211
Product	Name: Part No: Risk class: Basic UDI-DI	Big Jack 402500 I 734002311JACK28
Intended use/purpose	Big Jack is a robust remote control intended to support people who are unable to use a standard remote control due to motor or cognitive impairments. With up to six connected external control switches, the device can help the user control electronic equipment at home, including media devices and toys. The device is intended for indoor use.	
Directive(s)/Regulation(s)	MDR 2017/745/EU European Medical Device Regulation 2014/30/EU EMC directive 2011/65/EU and RoHS Restriction of hazardous substances directive 2015/863/EU 1907/2006/EC REACH The product does not include at all or less than 0,1% of chemicals in the candidate list "Substances of Very High Concern"	
Standards used	EN12182:2012 Assistive products for persons with disability - General requirements and test methods EN 60601-1-2:2015 Medical electrical equipment Part1-2 General requirements for basic safety and essential performance electromagnetic disturbances requirements and tests	

We declare under our sole responsibility that the product, to which this declaration relates, are in conformity with the above directive(s) and regulation(s).

Solna, 2021may28

Anna Wik, Manager Quality, Sustainability and Regulatory Affairs Abilia AB