



EU Declaration of Conformity

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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	GEWA Maxi 461130 I 734002311MAXI4Q
Intended use/purpose	GEWA Maxi is a large and simple to use remote control intended to support people who are unable to use a standard remote control due to motor-, cognitive or visual impairments. The device can help the user control electronic equipment at home, including TV sets, lighting, window- and door openers.	
Directive(s)/Regulation(s)	MDR 2017/745/EU European Medical Device Regulation 2014/30/EU EMC directive 2011/65/EU and 2015/863/EU RoHS Restriction of hazardous substances directive 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 IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance +AMD1:2012 +AMD2:2020 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