



EU Declaration of Conformity

Doc. ID: 22000-6

Manufacturer

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Phone: +46 8 594 694 00
Single Registration Number SE-MF-000005211

Product

Name: GEWA One
Part No: 461600, 461605, 461610, 461615
Risk class: I
Basic UDI-DI 734002311GONE4E

Intended use/purpose

The product helps users who are physically, cognitively and/or visually unable to use a standard remote control, to control electronic equipment at home, in school or at the workplace. The electronic equipment may include television sets, lighting, air conditioners, door openers, etc. Through an external switch (not included) or by tapping on the screen, the user can control electronic equipment by means of sending a wireless signal to the receiver of the selected device. The product is intended for indoor use only.

Directive(s)/Regulation(s)

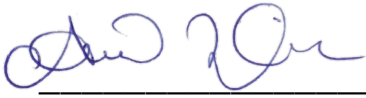
MDR 2017/745/EU	European Medical Device Regulation
2011/65/EU	RoHS Restriction of hazardous substances directive
1907/2006/EC	REACH The product does not include at all or less than 0,1% of chemicals in the candidate list "Substances of Very High Concern"

Standards used

SS-EN 55032	Electromagnetic compatibility of multimedia equipment - Emission requirement
ISO 16201:2006	Technical aids for persons with disability - Environmental control systems for daily living
IEC 60601-1:2005 + AMD 1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60950-1:2005 + AMD 1:2009 + AMD 2:2013	Information technology equipment - Safety - Part 1: General requirements

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