DECLARATION OF CONFORMITY

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AbleNet Inc
2808 Fairview Ave N.
Roseville, MN 55113 USA

Declares that the devices listed below conform to the following:

Model No.	Description
10033400	Jelly Bean Twist
10033500	Big Red Twist
100SPBK	Spec Switch – Black
100SPBL	Spec Switch – Blue
100SPG	Spec Switch – Green
100SPR	Spec Switch – Red
100SPY	Spec Switch – Yellow

Model No.	Description
100SBR	Snap Switch Cap – Big Red
100SJB	Snap Switch Cap – Jelly Bean
80030301	Jelly Bean Twist Tops – Semi Formal
80030302	Jelly Bean Twist Tops – Business Casual
80030401	Big Red Switch Tops – Semi Formal
80030402	Big Red Switch Tops – Business Casual

Medical Device Directive 2007/47EEC for Class I Devices

The CE marking has been affixed on the device according to EC Directive 93/42/EEC.

AbleNet Inc.

Date: 11/1/11

David Binczik
Vice President of Operations

European Contact: Rob Potman
Rednet AG
Roessinghsbleekweg 161
7522 AH Enschede
The Netherlands

Telephone: 31 53 4833088
FAX: 31 53 4833090

Declaration of Conformity

We declare that the 429000 Control Omni including

429010	Control Omni Docking station
429020	Control Omni Charger GEW100
429035	Control Omni Headset
429030	Control Omni Micro SD Card incl. USB adapter
429025	Control Omni Stylus
429045	Control Omni Rubber protection
890410	Control Omni Necklace
809210	Control Omni User guide SE/GB
809220	Control Omni Manual settings SE
809220	Control Omni Manual settings GB
100331-1616	Control Omni Manual Dockingstation SE/GB

conforms to the Medical Device Directive 93/42/EEC, Class 1 products,

SFS 1993:584 and LVFS 2003:11.

Referring standards:

Medical electrical equipment EN 60601-1, Edition 3.

SS-EN ISO 14971 Medical devices-Application of risk management to medical devices.

Date

June 17, 2011 .....

Erland Pontusson

CEO

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ABILIA
GEWA AB | FALCK IGEL

Declaration of conformity - Andromeda IR-REC8 BED

ABILIA

Process level	Abilia / Research and Developement / Documentation	**Document Category**	
Date Approved	22/11/2016 (Pontus Berglund)	**Prev Revision Date**	
Date Changed	22/11/2016 (Pontus Berglund)	**Next Revision Date**	
Validity Area			

EC/EEA Declaration of Conformity

In accordance with ISO/IEC 17050-1

Manufacturer

Abilia AB
Kung Hans väg 3, SE-191 22 Sollentuna, SWEDEN
Phone: +46 8594 694 00

Object of the declaration

Name:	Gewa Andromeda IR-REC8 BED
Model / Type:	IR-REC8 BED

Directive

MDD 93/42/EEC Class 1

Standards used

EN 12182:2012	Assistive products for persons with disability
EN 60950-1:2006 / A11:2009 /A1:2010/ A12:2011 / A2:2013	Information technology equipment – Safety – Part 1: General Requirements
EN14971:2000	Risk Analysis
EN 61000-6-2:2005, EN 61000-6-3:2007, EN12182:2012	Electromagnetic Interference
EN 61000-4-2:2009, EN 61000-4-3:2006 + A1:2008 + A2:2010, EN 61000-4-4:2012, EN 61000-4-5:2014, EN 61000-4-6:2014, EN 61000-4-8:2010, EN 61000-4-11:2004, CISPR 16-2-1:2014, CISPR 16-2-3:2010+A1	Electromagnetic Compatibility

We declare under our sole responsibility that the product(s), to which this declaration relates, are in conformity with the Essential Requirements Annex I of the above directive.

The declaration covers CE marked equipment/devices manufactured from the period commencing November 10th 2016 and until such time as a renewed conformity declaration is raised.

Gothenburg, November 21, 2016

Pontus Berglund, R&D Manager Abilia AB

EC/EEA Declaration of Conformity

In accordance with ISO/IEC 17050-1

Manufacturer

Abilia AB
Kung Hans väg 3, SE-191 22 Sollentuna, SWEDEN
Phone: +46 8594 694 00

Product description

Name:	GEWA Connect
Model / Type:	GEWA Connect

Directive(s)

MDD 93/42/EEC Class 1 EMC 2004/108/EG LVD 2006/95/EG	ErP 2009/125/EG RoHS2 2011/65/EU

Standards used

EN 12182:2012	Assistive products for persons with disability
EN 60065:2002 + A1:2006 + A11:2008 + A2:2010 + A12:2011	Audio, video and similar electronic apparatus. Safety requirements.
EN14971:2000	Medical devices – Application of risk management to medical devices
EN 55013:2001 + A1:2003 + A2:2006 EN 55020:2007 + A11:2011 EN 61000-3-2:2006 – A1: 2009 + A2:2009 EN 61000-3-3:2013	Electromagnetic Compatibility
IEC 62304:2006	Medical device software – Software life cycle process

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

The declaration covers CE marked equipment/devices manufactured from the period commencing October 27th 2017 and until such time a renewed conformity declaration is raised.

Gothenburg, October 27, 2017

Pontus Berglund, R&D Manager Abilia AB

Declaration of Conformity

We declare that receivers

419800	Andromeda IR-REC 1	419845	Andromeda IR-REC 4 OEM HM (+)
419812	Andromeda IR-REC 2	419846	Andromeda IR-REC 4 COVER HM (+)
419830	Andromeda IRZ-REC 4	419847	Andromeda IR-REC 4 OEM HM (-)
419835	Andromeda IRZ-REC 4 OUT	419848	Andromeda IR-REC 4 COVER HM (-)
419840	Andromeda IRZ-REC 4 COVER	419850	Andromeda IR-REC 4 WM
419842	Andromeda IRZ-REC 4 OEM DIN		

and detectors

419860	Andromeda IR-DET 3
419865	Andromeda IR-DET 15
419870	Andromeda IR-DET
419875	Andromeda IR-DET OEM

conforms to the Medical Device Directive 93/42/EEC, Class 1 products,

SFS 1993:584 and LVFS 2003:11.

Referring standards:

EMC and Radio; EN 300 220-2 V2.3.1:2010, EN 301 489-3 V1.4.1:2002

EN (IEC) 61000-6-2:2005, EN (IEC) 61000-6-3:2007

Electrical Safety; EN 60950-1:2006/A11:2009

SS-EN ISO 14971 Medical devices-Application of risk management to medical devices.

Date

March 09, 2013 .....

Hugo Petit

CEO

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