



DECLARATION OF CONFORMITY

PRODUCT FAMILY:

Assistive Technology Devices

PRODUCTS:

Clevy Keyboard* (USB, Bluetooth and Wireless RF)
Clevy Keyguard*

*See appendix I for all versions.

CLASSIFICATION:

Classified as Class I self-declaration devices by applying Rule No. 01 of Annex VIII of the Medical Devices Regulation (MDR 2017/745).

CONFORMITY ASSESSMENT ROUTE:

MDR 2017/745, Annex V – Self Declaration, Annex III - Generation and Maintenance of this Technical File to demonstrate compliance with the relevant General Safety & Performance Requirements (GSPR) of MDR 2017/745 - Annex I.

Alt. Medical B.V. hereby declares that the product has correct packaging and the relevant information and instructions required for use of the products. All manufacturing activities are subjected to the appropriate methods of internal quality control and inspection. We declare that the above-mentioned products meet the provisions of Medical Device Regulation MDR 2017/745 relating to medical devices and is classified in that field as a Class I non-invasive, non-sterile self-declaration medical device. All supporting documentation is retained at the premises of the Manufacturer. Alt. Medical B.V.'s Quality System and Technical Documentation is not subject to Notified Body surveillance; however, our devices are registered as Class I self-declaration products with Farmatec (NL).

NOTIFIED BODY:

Not applicable

MANUFACTURER:

Alt. Medical B.V.
Wasaweg 3a
9723 JD
Groningen
The Netherlands

Signature:

Date: 15-09-2021

B. van den Hoff
R&D Engineer, Alt. Medical B.V.

APPENDIX I

PRODUCT	COLOUR	LAYOUT	Font	SKU	GMDN	Basic UDI	UDI-DI
USB							
Clevy Keyboard	Multi	Australian	Lowercase	102918	65837	8718836180ALTATD	8718836180279
Clevy Keyboard	Multi	Belgian	Lowercase	102495	65837	8718836180ALTATD	8718836180163
Clevy Keyboard	Multi	Croatian	Uppercase	102926	65837	8718836180ALTATD	8718836180446
Clevy Keyboard	Multi	Danish	Lowercase	102497	65837	8718836180ALTATD	8718836180118
Clevy Keyboard	Multi	France	Uppercase	102493	65837	8718836180ALTATD	8718836180385
Clevy Keyboard	Multi	German	Uppercase	102496	65837	8718836180ALTATD	8718836180170
Clevy Keyboard	Multi	Italian	Uppercase	102490	65837	8718836180ALTATD	8718836180286
Clevy Keyboard	Multi	Norwegian	Uppercase	102499	65837	8718836180ALTATD	8718836180392
Clevy Keyboard	Multi	Norwegian	Both	102543	65837	8718836180ALTATD	8718836180125
Clevy Keyboard	Multi	Russian	Cyrillic	102508	65837	8718836180ALTATD	8718836180972
Clevy Keyboard	Multi	Serbian	Cyrillic	103010	65837	8718836180ALTATD	8718836180408
Clevy Keyboard	Multi	Spanish	Lowercase	102494	65837	8718836180ALTATD	8718836180262
Clevy Keyboard	Multi	Spanish	Uppercase	103067	65837	8718836180ALTATD	8718836180705
Clevy Keyboard	Multi	Swedish	Uppercase	102498	65837	8718836180ALTATD	8718836180460
Clevy Keyboard	Multi	United Kingdom	Lowercase	102500	65837	8718836180ALTATD	8718836180606
Clevy Keyboard	Multi	Us-international	Lowercase	102488	65837	8718836180ALTATD	8718836180019
Clevy Keyboard	Multi	Us-international	Uppercase	102565	65837	8718836180ALTATD	8718836180293
Clevy Keyboard	Yellow	Spanish	Uppercase	103049	65837	8718836180ALTATD	8718836180804
Clevy Keyboard	Yellow	Us-international	Lowercase	102782	65837	8718836180ALTATD	8718836180439
Clevy Keyboard	Contrast	Danish	Uppercase	102870	65837	8718836180ALTATD	8718836180743
Clevy Keyboard	Contrast	German	Uppercase	102569	65837	8718836180ALTATD	8718836180255
Clevy Keyboard	Contrast	Italian	Uppercase	102527	65837	8718836180ALTATD	8718836180453
Clevy Keyboard	Contrast	Norwegian	Uppercase	102548	65837	8718836180ALTATD	8718836180132
Clevy Keyboard	Contrast	Swedish	Uppercase	102570	65837	8718836180ALTATD	8718836180736
Clevy Keyboard	Contrast	Us-international	Uppercase	102526	65837	8718836180ALTATD	8718836180026
Wireless RF							
Clevy Keyboard	Multi	Australian	Lowercase	102871	65837	8718836180ALTATD	8718836180897
Clevy Keyboard	Multi	Belgian	Lowercase	102819	65837	8718836180ALTATD	8718836180194
Clevy Keyboard	Multi	Croatian	Uppercase	102927	65837	8718836180ALTATD	8718836180903
Clevy Keyboard	Multi	France	Uppercase	102567	65837	8718836180ALTATD	8718836180910
Clevy Keyboard	Multi	German	Uppercase	102564	65837	8718836180ALTATD	8718836180200
Clevy Keyboard	Multi	Italy	Uppercase	102563	65837	8718836180ALTATD	8718836180835
Clevy Keyboard	Multi	Russian	Cyrillic	102783	65837	8718836180ALTATD	8718836180378
Clevy Keyboard	Multi	Serbian	Cyrillic	103011	65837	8718836180ALTATD	8718836180927
Clevy Keyboard	Multi	Spanish	Lowercase	102562	65837	8718836180ALTATD	8718836180934

Clevy Keyboard	Multi	Spanish	Uppercase	103069	65837	8718836180ALTATD	8718836180729
Clevy Keyboard	Multi	United Kingdom	Lowercase	102542	65837	8718836180ALTATD	8718836180323
Clevy Keyboard	Multi	US-international	Lowercase	102547	65837	8718836180ALTATD	8718836180941
Clevy Keyboard	Multi	US-international	Uppercase	102549	65837	8718836180ALTATD	8718836180187
Bluetooth							
Clevy Keyboard	Multi	Australian	Lowercase	102918	65837	8718836180ALTATD	8718836180484
Clevy Keyboard	Multi	Belgian	Lowercase	102495	65837	8718836180ALTATD	8718836180491
Clevy Keyboard	Multi	Croatian	Uppercase	102926	65837	8718836180ALTATD	8718836180569
Clevy Keyboard	Multi	Danish	Lowercase	102497	65837	8718836180ALTATD	8718836180873
Clevy Keyboard	Multi	France	Uppercase	102493	65837	8718836180ALTATD	8718836180507
Clevy Keyboard	Multi	German	Uppercase	102496	65837	8718836180ALTATD	8718836180514
Clevy Keyboard	Multi	Italy	Uppercase	102490	65837	8718836180ALTATD	8718836180521
Clevy Keyboard	Multi	Norwegian	Uppercase	102499	65837	8718836180ALTATD	8718836180637
Clevy Keyboard	Multi	Norwegian	Both	102543	65837	8718836180ALTATD	8718836180811
Clevy Keyboard	Multi	Serbian	Cyrillic	103012	65837	8718836180ALTATD	8718836180576
Clevy Keyboard	Multi	Spanish	Lowercase	102950	65837	8718836180ALTATD	8718836180538
Clevy Keyboard	Multi	Spanish	Uppercase	103068	65837	8718836180ALTATD	8718836180712
Clevy Keyboard	Multi	Swedish	Uppercase	103037	65837	8718836180ALTATD	8718836180651
Clevy Keyboard	Multi	United Kingdom	Lowercase	102947	65837	8718836180ALTATD	8718836180316
Clevy Keyboard	Multi	Us-international	Lowercase	102917	65837	8718836180ALTATD	8718836180477
Clevy Keyboard	Multi	US-international	Uppercase	102953	65837	8718836180ALTATD	8718836180545
Clevy Keyboard	Yellow	US-international	Lowercase	103022	65837	8718836180ALTATD	8718836180552
Clevy Keyboard	Contrast	Danish	Uppercase	103041	65837	8718836180ALTATD	8718836180767
Clevy Keyboard	Contrast	German	Uppercase	102988	65837	8718836180ALTATD	8718836180965
Clevy Keyboard	Contrast	Italian	Uppercase	102987	65837	8718836180ALTATD	8718836180590
Clevy Keyboard	Contrast	Norwegian	Uppercase	103039	65837	8718836180ALTATD	8718836180781
Clevy Keyboard	Contrast	Swedish	Uppercase	103040	65837	8718836180ALTATD	8718836180774
Clevy Keyboard	Contrast	Us-international	Uppercase	102986	65837	8718836180ALTATD	8718836180583

PRODUCT	COLOUR	SKU	GMDN	Basic UDI	UDI-DI
Clevy Keyguard					
Keyguard	Transparent	102177	43126	8718836180ALTATD	8718836180248
Keyguard Scandinavia	Transparent	102560	43126	8718836180ALTATD	8718836180033
Keyguard Dyscover	Transparent	102695	43126	8718836180ALTATD	8718836180750