EU Declaration of Conformity

Statement of Use: Verify status before each use

This declaration is issued under the sole responsibility of Alerta Medical Ltd.

We, the manufacturer, hereby declare that the below-mentioned medical devices are designed and manufactured by Alerta Medical Ltd. in accordance with the scope of a quality system which meets the requirements of the European Communities' Council Regulation 2017/745/EC in accordance with Annex I, General Safety and Performance Requirements and Annex IX.

All supporting documentation is retained at the premises of the manufacturer.

Legal Manufacturer	Alerta Medical Ltd.				
Legal Manufacturer Address	4 Symington Place, Riverside Business Park, Irvine, KA11 5DE, UK.				
SRN (Single Registration Number)	GB-MF-000013708				
Product Family	Patient Transfer System, Manual				
Product/Trade Name	Reference Schedule				
Product Code	Reference Schedule				
Intended Purpose	A transfer assist unit intended for use by users who have difficulty walking to enhance mobility with minimal caregiver assistance. It is intended to promote user engagement and enhances mobility.				
Basic UDI-DI	506061453MoveAssistKA				
GMDN Code	46148 - Patient transfer system, manual	**EMDN Code**	V08050399 - Patient transfer lifts - others	**CND Code**	V08050399 - Patient transfer lifts - others
Risk Classification – **(according to Annex VIII of regulation 2017/745)**	Class I	Rule 1			
Sterilisation Method	Non-sterile				
Conformity Assessment	Article 52, section 7 of the Medical Device Regulation 2017/745/EC Technical Documentation: Annex II and Annex III of regulation 2017/745				
Common Specifications	None				
Standards	• ISO 20417:2021 • BS EN ISO 10993-1:2020 • ISO 15223-1:2021 • EN ISO 14971:2019/A11:2021				

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	• ISO 14971:2019+A11:2021	
Authorised Representative	CS Lifesciences Europe Limited Email: eurep@cslifesciences.com	The Black Church, St Mary's Place, Dublin 7 Dublin D07 P4AX Ireland
	SRN (Single Registration Number)	
	IE-AR-000004113	
Notified Body for CE Mark	Not Applicable	Not Applicable
EC Certificate for CE Mark	Not Applicable	Not Applicable
Quality System Certificate	Alerta Medical Ltd. declares that its products are designed and manufactured in accordance with the scope of a quality system which meets the requirements of Article 10 of the Medical Device Regulation EU 2017/745.	

Approved on behalf of Alerta Medical Ltd. .

Ian Lindberg **CEO**	
Date, town, and country of signing	**3rd May 2024, Irvine, United Kingdom**

Schedule: Product Codes/ Catalogue Numbers

Product Code/ Catalogue Number	Product Name
ALT-ST200	Alerta ST 200 MoveAssist