SELF-DECLARATION OF CONFORMITY

Manufacturer (Name and Address)	Amico Mobility Solutions Corp, 122B East Beaver Creek Rd, Richmond Hill, Canada, L4B 1G6 This declaration of conformity is issued under the sole responsibility of the manufacturer.
EU Authorized Representative	AJW Technology Consulting GmbH Breite Str. 3, 40213 Düsseldorf, Germany
Product group	Amico GoLift 400, 700 & 1000 (including all accessories, e.g. hanger bars, track components, trollies, power supplies)
Class of Device	Class I (according EU MDR 2017/745 Annex VIII)
EMDN Code	V08050302
Basic UDI-DI	684706572400699
SRN	DE-AR-000004999
Intended purpose	Patient hoisting
Certificate Number	Q5 001736 0006 Rev 01 (ISO 13485:2016)
Legislation	The object of the declaration is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices the relevant Union harmonization legislation: Amendment of 11 May 2022 to Implementing Decision (EU) 2021/1182
Standards Applied	- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 - Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery - EN ISO 10535:2006 - Hoists for the transfer of disabled persons -Requirements and test methods (ISO 10535:2006) - EN60601.1.2:2015 – Medical electrical equipment – Part1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests - EN60601-1:2006 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - EN 60601-2-6:2010 – Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability - EN ISO 14971-2019 – Medical devices – Application of risk management to medical devices (ISO 14971:2019) - EN ISO 13485-2016 – Medical Devices – Quality Management systems – Requirements for regulatory purposes (ISO 13485:2016) - Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance (R2012) [AAMI ES60601-1:2005 +AC1;A2] - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (R2013) [CSA C22.2#60601-1:2008 Ed.2 +C2] - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability [IEC 60601-1-6:2010 Ed.3] - Medical Devices - Application Of Usability Engineering To Medical Devices [IEC 62366:2007 Ed.1]
Signature & Date	February 20, 2025	Pradeep Prabhakar Global Quality & Regulations Manager