EU Declaration of Conformity

The EU declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacturer:	*Automax.dk*	
Address:	**Østergade 62 6623 Vorbasse**, *Denmark*	
Trade name(-s):	**Kørestols-stolen**	
SRN:		

Product Name:	**Kørestols-stolen**		
Type / Model:	1008-001	**Basic UDI-DI:**	
Intended purpose:	Aflastning af kørestolsbruger		
Class / rule / annex: *(EU 2017/745)*	Class I, Active device rule 13, Conformity assessment annex II and III		

The device covered by this EU declaration of conformity is in conformity with the following Regulation and harmonized standards:

Regulation EU 2017/745 of the European Parliament and of the Council of 5. April 2017 on Medical devices (MDR)

Harmonized standards used:

EN ISO 14971:2019	Application of risk management to medical devices
EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 12100:2010	basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process.
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62366-1:2015	Application of usability engineering to medical devices

DK- *6623 Vorbasse 14-11-2023*
Place and Date

Max Birkelund, *CEO*