EU DECLARATION OF CONFORMITY

Rail components

Manufacturer	V. Guldmann A/S Graham Bells Vej 21-23A DK-8200 Aarhus N Phone +45 8741 3151 SRN: DK-MF-000003602
Distributor/ Subsidiary	Company
	Address
	Country
	Phone

Hereby declare that the requirements specified in EU Regulation 2017/745 (MDR) regarding medical devices have been fulfilled in relation to the below listed device groups. The devices are also in conformity EU Directive RoHS 2011/65/EU and EU Directive REACH - 1907/2006/EC.

The declared medical devices comply where appropriate, with the following European standards ISO 10535 Hoist for transfer of disabled persons – Requirements and test methods, IEC 60601-1 Medical electric equipment – Part 1 General requirments for basic safety and essential performance

Guldmann A/S is certified as meeting quality management systems according with standards ISO 9001 and ISO 14001. Where appropriate, we comply with ISO 13485 Medical Devices – Quality Management Systems – Requirements for regulatory purposes and FDA 21 CFR part 820.

Device Group	**Rail components** Rails, Brackets, Drive motor for traverse, Positioning lock, Turntable, Switch track 60°, Switch track 90°, Combi-lock Class I, Rule 13
Basic UDI-DI	15707287railcomponentF3
Intended purpose	The intended purpose of Guldmann rail components is to assist moving, routing and locking the hoist and railsystem.

On behalf of V. Guldmann A/S

Skejby, 2022.04.29

Place and date of issue

Ulrik Møller, Technical Manager

Guldmann™