EU DECLARATION OF CONFORMITY

Free-standing rail system

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 declared medical devices comply where appropriate, with the following European standards ISO 10535 Hoist for transfer of disabled persons – Requirements and test method. 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	**Free-standing rail system** Free-standing rail system adjustable, Free-standing room-covering rail system, adjustable, Free-standing room-covering rail system, height adjustable, SwingLift II Class I, Rule 1
Basic UDI-DI	15707287freestanding5Z
Intended purpose	Free-standing systems are intended to support the ceiling hoist in a movable systems that is not suspended from a building or structure.

On behalf of V. Guldmann A/S

Skejby, 2021.07.06

Place and date of issue

Ulrik Møller, Technical Manager

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