EU DECLARATION OF CONFORMITY

Ceiling Hoist

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, IEC 60601-1, EN 62304.

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	**Ceiling hoist** GH3, GH3+, GH3 Twin, GH1, GH1 Q, GH1 F, GHZ Class I, Rule 13 in accordance with the rules set out in Annex VIII of EU 2017/745 (MDR)
Basic UDI-DI	15707287ceillinghoistX3
Intended purpose	The ceiling hoist is intended for lifting and transferring a person with disabilities and for walking training.
Conformity of optional module	In accordance with the requirements in Directive 2014/31/EU, the Guldmann NAWI accuracy class III scale module is a non-automatic weighing instrument. Notified Body, FORCE Certification, No 0200, has certified the product as described in the EU Type Examination Certification No. 0200-NAWI-03847 as well as the Quality Management System in accordance with NAWI Module D and relevant standards, including DS/EN 45501:2015 Metrological aspects of non-automatic weighing, with exemption as to requirements for weighing down.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

On behalf of V. Guldmann A/S

Skejby, 2023.06.30

Place and date of issue

Ulrik Møller, Technical Manager

Guldmann™