EU DECLARATION OF CONFORMITY

Portable ramps for wheelchairs

Manufacturer

Company

Sumitomo Rubber Industries, Ltd

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3-6-9, Wakinohama-cho, Chuo-ku, Kobe, Hyogo

651-0071, Japan

Phone

+81-79-458-8453

Distributor and authorized

representative

Company

V. Guldmann A/S

Address

Graham Bells Vej 21-23A DK-8200 Aarhus N

Phone

+45 8741 3151 DK-AR-000028722

Hereby declare under the sole responsibility of the manufacturer 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 with EU Directive RoHS 2011/65/EU and EU Regulation REACH - 1907/2006/EC.

The declared medical device complies with the following Japanese Industrial Standards "JIS T9207: Portable ramps for wheelchairs" general requirements and test methods as necessary.

Manufacturing contractor for Sumitomo Rubber Industries, Ltd, is certified as meeting quality management systems accordance with standards ISO 9001.

Guldmann A/S is certified as meeting quality management systems according with standards ISO 9001 and ISO 14001. Guldmann A/S also complies with ISO 13485 Medical Devices - Quality Management Systems - Requirements for regulatory purposes and FDA 21 CFR part 820.

Device Group

Portable ramps for wheelchairs

Part number

30100-070, 301400-085, 30100-125, 30100-134, 30100-150, 30100-165, 30100-205,

30200-047, 30200-072

Risk class

Class I, Rule 1

Intended purpose

Portable ramps are intended for helping wheelchair users overcome height differences in the

physical surroundings.

This declaration of conformity is issued under the sole responsibility of the manufacturer, Sumitomo Rubber Industries, Ltd

Kobe, 2023.05.08

Place and date of issue

Hyogo, [Koji Tabata], General Manager

C. Taliata